

COMPARATIVE STUDIES OF CONCEPTUAL
DESIGN AND QUALIFICATION PROCEDURES
FOR A MARS PROBE/LANDER

FINAL REPORT
VOLUME IV: STERILIZATION
APPENDIX C

Prepared by

AVCO CORPORATION
AVCO SPACE SYSTEMS DIVISION
Lowell, Massachusetts

AVSSD-0006-66-RR
Contract NAS 1-5224
Modification No. 7

22 October 1966

APPROVED

T. H. Rider / DHT
T. H. Rider
Project Manager

Prepared for

LANGLEY RESEARCH CENTER
LANGLEY STATION
Hampton, Virginia 23365



71-76200	(THRU)	
68	(CODE)	
68	(CATEGORY)	
68	(PAGES)	
68-122512	(NASA CR OR TMX OR AD NUMBER)	

FOREWORD

Submission of this report (Appendix C of Volume IV: Sterilization) completes the work contracted under NAS1-5224: Comparative Studies of Conceptual Design and Qualification Procedures for a Mars Probe/Lander. Appendix C specifically presents the work required under Modification 7 of the contract.

The content of Appendix C presents and discusses data obtained from 216 computer runs. In these computer runs, variations were made in the level of microbial contamination available from the various sources and in the contamination control cycles.

The data obtained in the Modification 7 work, in combination with the 22 computer runs made under the original contract, allowed a significant expansion of the nomograms presented in the text of Volume IV. In addition, some of the data included in Volume IV are inaccurate, due to errors in manual calculations to modify the computer-generated burden values so that the burden identified would be that only on the capsule and the inside surface of the sterilization canister. In Modification 7, a more accurate method for the computation was developed and incorporated into the machine runs. Consequently, the information contained in this appendix is complete and essentially self-sustaining; except for general information, it is not necessary to refer to the separately bound text of Volume IV.

The conduct of the study and the technical preparation of this appendix involved the participation and close coordination of several people, all of whose contributions were important to the end results.

The major contributions of Mr. S. Paul Yannalfo are particularly appreciated by the Project Manager.

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1.0 INTRODUCTION

The Avco Space Systems Division, under contract to the NASA Langley Research Center (Contract No. NAS 1-5224), has completed "Comparative Studies of Conceptual Design and Qualification Procedures for a Mars Probe/Lander." A part of the contract work was to study and evaluate the impact of sterilization requirements on vehicle system design, fabrication, and mission. The basic contract work was reported in Volume IV, "Sterilization," of the final report, dated 11 May 1966.

CCN No. 3 (Modification 7) was issued on 13 May 1966 to amend the contract by expanding the scope of work required in the Statement of Work, L-5295C, paragraph 4.4.1, "Microbial Burden Sensitivity."

This appendix contains the complete results of the work required under paragraph 4.4.1, as amended.

1.1 PARAMETER VARIATIONS

The variations in parameters that were used in the Microbial Burden Sensitivity study are shown in Table I. Under the column heading "Part II," this listing presents the parametric values used in the work of the original contract. Modification 7 to the original contract introduced the parametric variations shown under the column "Variations."

The work performed in the original contract consisted of 22 computer runs. These initial runs evaluated the parametric values listed under Part II for four weight classes. The insight provided from the results of the initial runs allowed formulation of 18 additional runs per weight class under Modification 7 of the contract. As this additional work progressed, it was found desirable to include complementary variations of mated area, fallout, die-off, and electrostatic factor. These complementary variations required 14 additional computer runs per weight class, and were accomplished within allowed contract costs. These complementary runs are shown in Table II.

In summary, the results presented in this volume (Appendix C) are based on 54 computer runs per weight class -- a total of 216 runs.

TABLE I

STUDY PARAMETER

Parameter	Part II	Variations
Handling	1900 organisms/ in ² /contact	19, 190, 19,000 organisms/in ² / contact
Mated area	17-percent average	(1.7 percent), (3.4 percent), (8.5 percent)
Point of flight acceptance (FA) Application	See note*	
(FA) effectivity	12D	6D, 8D, 10D
ETO effectivity	4D	2D, 6D, 8D
Clean room quality	2D	0.5D, 1.0D, 1.5D

*During Part II of the study, the flight acceptance (FA) heat cycle was taken to be applied at the component level before any final assembly had started. To determine the effect that delaying the application of the cycle has on burden, the heat cycle can be considered as applied to the following alternate points:

- a) Each of the three electronic modules, prior to their being assembled to the payload structure and to the entry shell after installation of the diagnostic sensors
- b) The payload structure, after installation of the electronic modules
- c) The payload structure, after assembly of the flight capsule to flight spacecraft adapter but before assembly of the structure to the entry shell; to the entry shell, after installation of three pressure transducers.

TABLE II

ADDITIONAL COMPUTER RUNS (NO COST)

Mated Area (percent)	Fallout	Electrostatic Factor	Die-off	ETO	Clean Room	Flight Acceptance
17	128	10	30	no	no	yes
17	128	10	30	no	yes	yes
17	128	10	30	no	yes	no
17	128	10	30	yes	no	yes
17	32	5	90	no	no	yes
17	32	5	90	no	yes	no
17	32	5	90	no	yes	yes
3.4	128	10	30	yes	no	no
3.4	128	10	30	yes	yes	no
3.4	128	10	30	yes	yes	yes
3.4	128	10	30	no	no	yes
3.4	128	10	30	no	yes	yes
3.4	128	10	30	no	yes	no
3.4	128	10	30	yes	no	yes

2.0 DISCUSSION OF EXTENDED STUDY

This section discusses the work performed under Modification 7 (CCN No. 3). Modification 7 consists of the performance of runs 23 through 54, listed in Table III. Discussion of runs 1 through 22 was included in the text of Volume IV (AVSSD-0006-66-RR, Contract NAS 1-5224). The results and conclusions drawn from all computer runs (1 through 54) are presented in Section 4 of this appendix.

The original work (runs 1 through 22) accounted for the following variables as a function of total pre-sterilization burden on a 2000-pound vehicle:

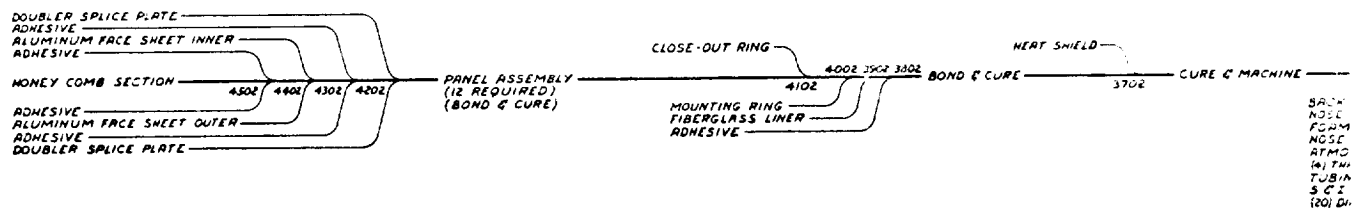
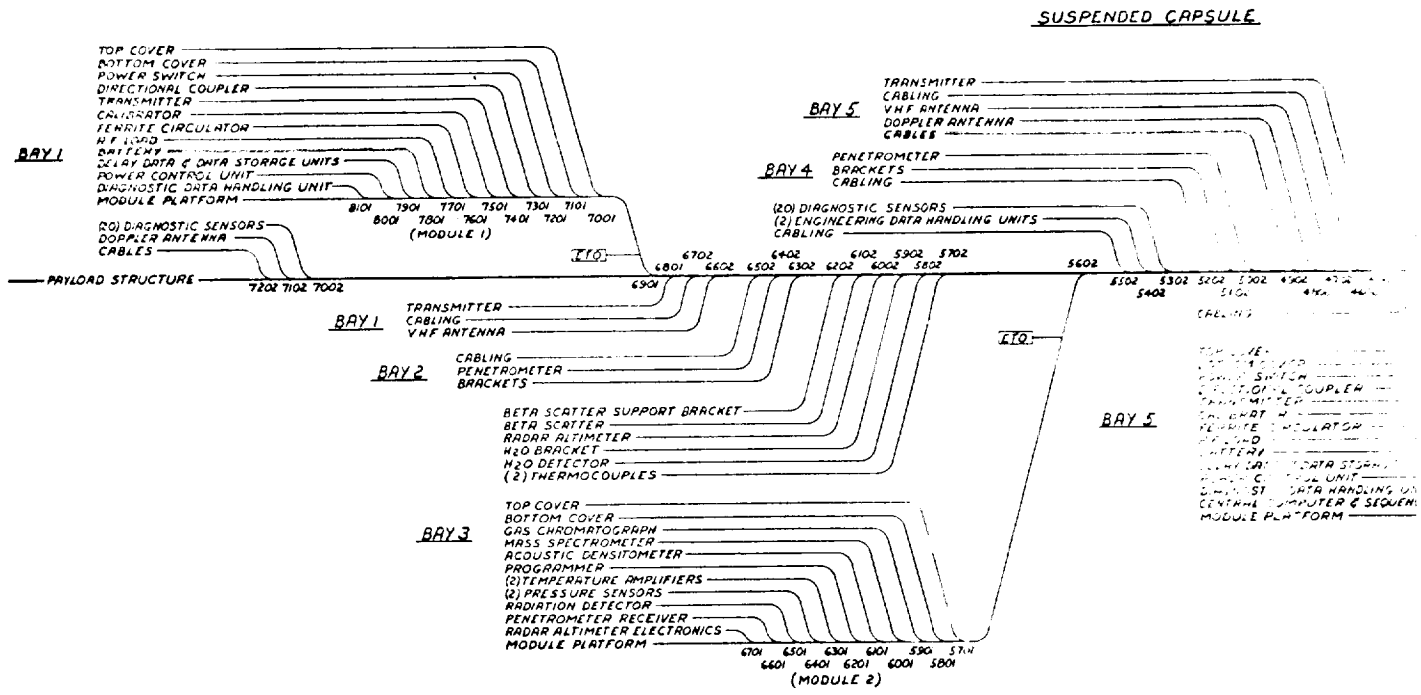
- a) Fallout rate (32 to 128, or $3/\text{in}^2/\text{day}$)
- b) Electrostatic Factor (1 to 10)
- c) Die-off rate (30 to 99 percent)
- d) Application of ETO (yes or no, 4D effectivity)
- e) Use of Clean room (yes or no, 2D effectivity)
- f) Application of flight acceptance (FA) heat cycle (yes or no, 12D effectivity at component level)

The extended scope of Modification 7 complimented the original variables with the following variables:

- 1) Handling (19 to 19,000 organisms/ $\text{in}^2/\text{control}$)
- 2) Mated area (factors of 1/10, 1/5, and 1/2 of original)
- 3) FA heat cycle effectivity (6, 8, and 10D)
- 4) ETO effectivity (2, 6, and 8D)
- 5) Clean room quality (0.5, 1.0, and 1.5D)
- 6) Point of FA application (three at various stages of completion)
- 7) Weight (1000, 2000, 4000, and 10,000 pounds)

Table III is a summary of the basic data obtained from all computer runs. The table presents the results for 54 burden-analysis runs for each of the 4 weight class vehicles considered.

The remainder of this section discusses runs 23 through 54.



2.1 RUNS 23, 24, AND 25

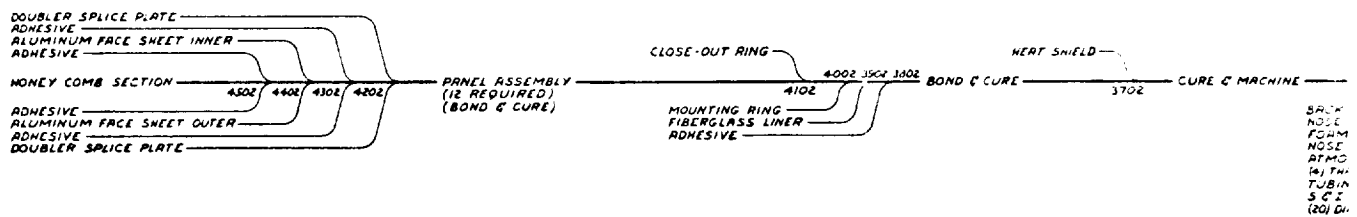
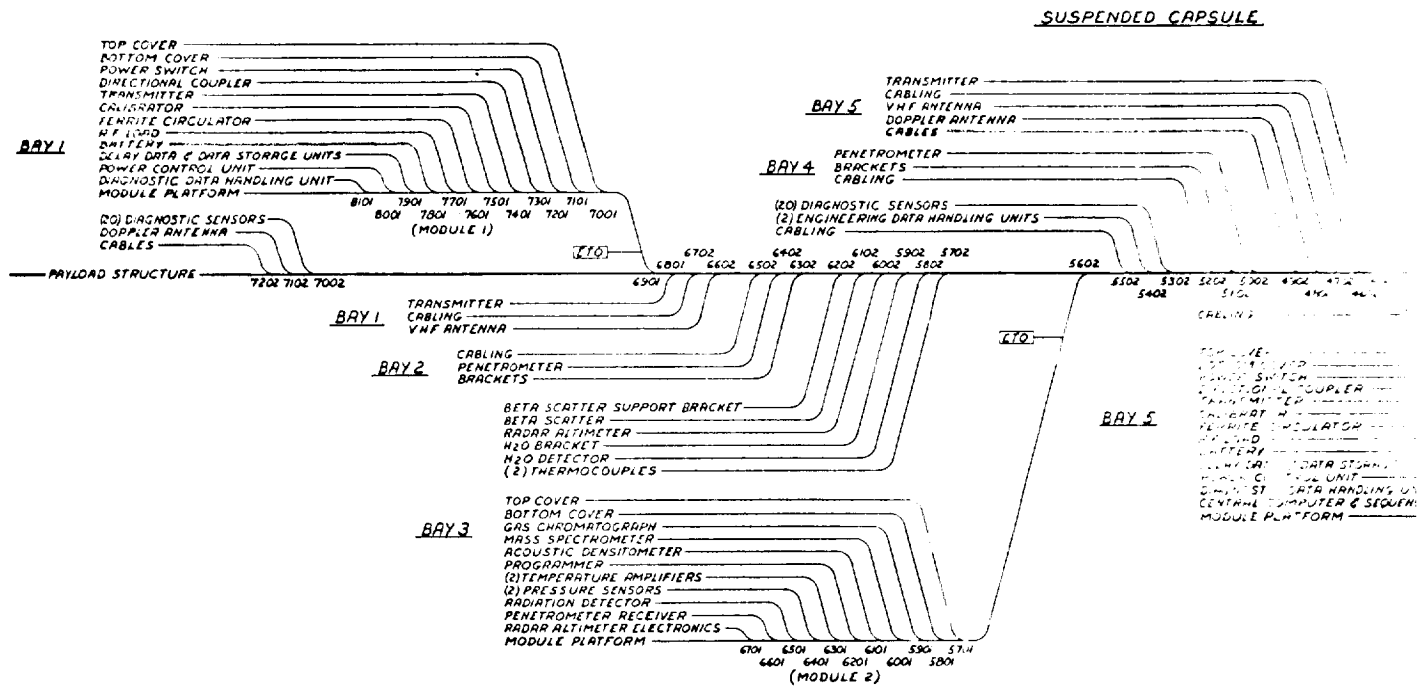
The purpose of these runs is to investigate variations, as a function of handling, in the burden deposited on the vehicle. Handling burden is a function both of the number of times that a particular element is handled and the amount of burden deposited on the element each time the element is handled. The approach taken in these runs is to vary the burden deposited per handling to evaluate the influence of personnel cleanliness. In Table III, Column H (Handling), the values for handling burden for these runs varies from 19 organisms per square inch per contact to 19,000 organisms per square inch per contact. Run number 1 accounts for the nominal value of 1900 organisms and, except for the handling value, had parameters identical to runs 23, 24, and 25. From Table III, it is apparent that for each of the four weights there is very little change in total burden as a function of handling burden at the lower two levels of 19 and 190 organisms per square inch per contact. When the burden approaches higher values of 1900 or 19,000 organisms per square inch per contact, the total burden of the vehicle increases significantly.

2.2 RUNS 26, 27, AND 28

These runs were set up to evaluate the effect of changes in the ratio of mated area to total vehicle area. In the original computer runs, the mated area of the vehicle studied was found to be approximately 17 percent of all surfaces. This is a very conservative value and tends to magnify that portion of the burden that is not accessible to ETO decontamination. The purpose of these runs is to investigate the effect of reducing this mated area to values of 1/10, 1/5, and 1/2 of its original value. The run-26 mated-area column of Table III is based on a mated area of 1/10 of the original area (1.7 percent instead of 17 percent). Run 27 is based on 1/5 the original area, run 28 on 1/2. From the results of these three runs, it is obvious that changing the mated area alters in no way the final burden level. The reason for this is that ETO, clean room, or flight acceptance controls have not been used. In each of these cases, the ratio of mated burden to external burden has changed. Thus, where the mated area is less, a greater portion of the total burden is exposed on the surface and exposable to ETO. Further discussion on mated area can be found in Section 2.9, run 48 through 54.

2.3 RUNS 29, 30, AND 31

The purpose of these runs is to evaluate changes in the point of application of flight acceptance heat cycle in the assembly sequence. For this discussion, reference is made to Figure 1, assembly flow chart. In the original set of computer runs the flight acceptance heat cycle was applied only at the component level. Each item on the chart was considered to have been exposed to this heat cycle before the item entered the assembly process.



In these runs, the effect on total burden of subjecting various levels of sub-assemblies to this heat cycle was evaluated. In Table III, column FAA, run 29, the flight acceptance heat cycle was applied at the module level. This means that the flight acceptance heat cycle is considered to be applied at the following control points and levels: 6901, 5602, and 4301, for modules 1, 2, and 3. In this run, the remaining elements of the capsule are considered to be exposed to the heat cycle at a component level. In the case of run 30, the flight acceptance cycle was applied at payload-level control-point and level 4201. Modules 1, 2, and 3; elements assembled in bay 5, bay 4, bay 1, and bay 2; and the other components not identified with bays, were considered exposed in a single cycle. In run 31, column FAA indicates that the flight acceptance heat cycle was applied at the point of payload plus. This heat cycle application was made at level and control points 1501 and 1201 in a manner that exposed the complete combination of the payload structure, the three modules, and associated components. Both parachutes, the rocket engine, and the flight capsule to flight spacecraft adapter were also exposed for run 31. In addition, at control-point and level 1201, the complete entry shell assembly was exposed to the heat cycle. The results of these runs indicate that as the flight acceptance heat cycle is applied at a point closer to the completion of the assembly of the vehicle, the final burden is substantially reduced in all four weight classes. The reason for this is that the exercise of the heat cycle at a later point in time kills greater amounts of burden; each heat cycle kills essentially all of the burden of the vehicle up to that point.

2.4 RUNS 32, 33, AND 34

The purpose of these runs is to evaluate the effect of varying the effectivity of the flight acceptance heat cycle. In all of the previous runs, the flight acceptance heat cycle was considered to have a 12-D effectivity. These runs consider 6-, 8-, and 10-D effectivity, in each case, the cycle was applied at the component level. The results indicate that there is no change in the total burden as a function of change in the level of flight acceptance heat cycle. The reason for this lack of any change in the total burden is that the kill capability of a 6-decade flight acceptance heat cycle is sufficient to kill all of the burden of the vehicle. Therefore, the application of a heat cycle with 8, 10, or 12 decades of kill capability does nothing more than overkill the burden. From this study, it seems quite clear that from a sterilization point of view nothing is gained by exercising a flight acceptance heat cycle of more than 6 decades of kill effectivity. This does not alter the fact that 10- or 12-decade heat may be required from a reliability point of view.

2.5 RUNS 35, 36, AND 37

These runs were made to show the effect of changes in the kill capability of ethylene oxide (ETO) over a range of 2 to 8 decades. The point of application of ETO was the same as that in the original study. The application points were

2 decades cleaner than a normal room; e. g. , where a fallout rate of 128 organisms per square inch per day was considered normal, the fallout in a clean room would be 1.28 organisms per square inch per day, or 1 percent of the normal fallout. For the follow-on study, it was desired to measure the impact of gradation in clean room quality. Clean room quality was taken as ranging from 0.5 to 1.5 decades. To account for clean room qualities identified with fractional numbers, the following procedure was used: In a given run, where a clean room of any level is applied, the fallout rate is taken as the normal fallout rate time 10^{-x} , where x is the decade value. Therefore, in the case of a 2-decade clean room and a fallout rate of 128 organism per square inch per day in a normal environment, the fallout in the clean room is calculated as follows:

$$128 \times 10^{-2} = \frac{128}{100} = 1.28.$$

In a similar manner, where a clean room quality is taken to be 0.5 decades, the fallout rate is calculated as follows:

$$128 \times 10^{-0.5} = \frac{128}{\sqrt{10}},$$

or a fallout rate of approximately 40.5 organisms per square inch per day.

3.6 POINT OF FLIGHT ACCEPTANCE APPLICATION

In addition to the application of flight acceptance heating at a component level, FA heating is considered to apply at the following alternative levels for this study extension (Figure 1):

- a) Each of the three electronic modules, prior to module assembly to the payload structure and to the entry shell after installation of the diagnostic sensors
- b) The payload structure after installation of the electronic modules
- c) The payload structure, after assembly of the flight capsule to the flight spacecraft adapter but before assembly of the structure to the entry shell; to the entry shell after installation of the three Pressure Transducers.

3.7 WEIGHT

The original study was performed using the design generated for the entry-from-orbit case. This vehicle weighs approximately 2000 pounds. In this follow-on study, evaluation was desired of the effect of weight changes on total

vehicle burden. For this purpose, weight classes of 1,000, 4,000, and 10,000 pounds were used. Since weight, as such, is not an input to the biological burden analysis program, changes in weight as functions of linear dimensions, volumes, and numbers of electronic components were generated. The following logic was applied to determine differences between weight classes of vehicles.

3.7.1 Volume

By assuming constant specific gravities for each element considered by volume, such as rocket fuel, weight can be taken as a direct function of volume: to double the weight, we simply double the volume.

3.7.2 Area

By continuing the assumption that specific gravities of components are the same in vehicles of different weight classes, we are able to conclude that were the volume of any part to double, the length of any dimension on that part would increase by a factor of $2^{1/3}$, or approximately 1.26, which is the factor for the length change in any one direction to double the weight of a particular element. The corresponding factor of area change for double weight is $(1.26)^2$, or 1.5874. Knowing this ratio, we can determine from the original set of data the equivalent area of a part were its weight doubled.

Figure 2 has been generated to show ratios of volume and weight, area, and length for each vehicle weight from 0 to 10,000 pounds. The reference vehicle is the 2,000-pound vehicle.

3.7.3 Electronic Components

Figure 2 shows a weight ratio for black box, or electronic component parts. As the weight of a vehicle increases, the weight of parts in electronic components, such as resistors, diodes, and so forth, do not increase, although it is possible that more such parts are used to increase instrument payload. To account for this variation in electronic complexity of vehicles and in the function of weight change, the number of electronic parts is assumed to change as a function of weight. The information that generated the dashed line shown on Figure 2 was obtained from the earlier study and, also, from the study done for Ames Research Center for a Mars atmosphere probe. Analyses of both these vehicles showed that the number of electronic parts in the smaller vehicle is approximately half of those in the larger (Langley) vehicles. Extrapolating this line linearly to the 10,000-pound weight class indicates that a 10,000 pound vehicle would have three times as many electronic parts as a 2,000-pound vehicle. This seems fairly realistic, inasmuch as the larger vehicle would probably contain much more mechanical articulation and complication than the 2,000-pound vehicle; the increased weight of electronic parts probably would be a smaller function than the increase of total weight of the vehicle.

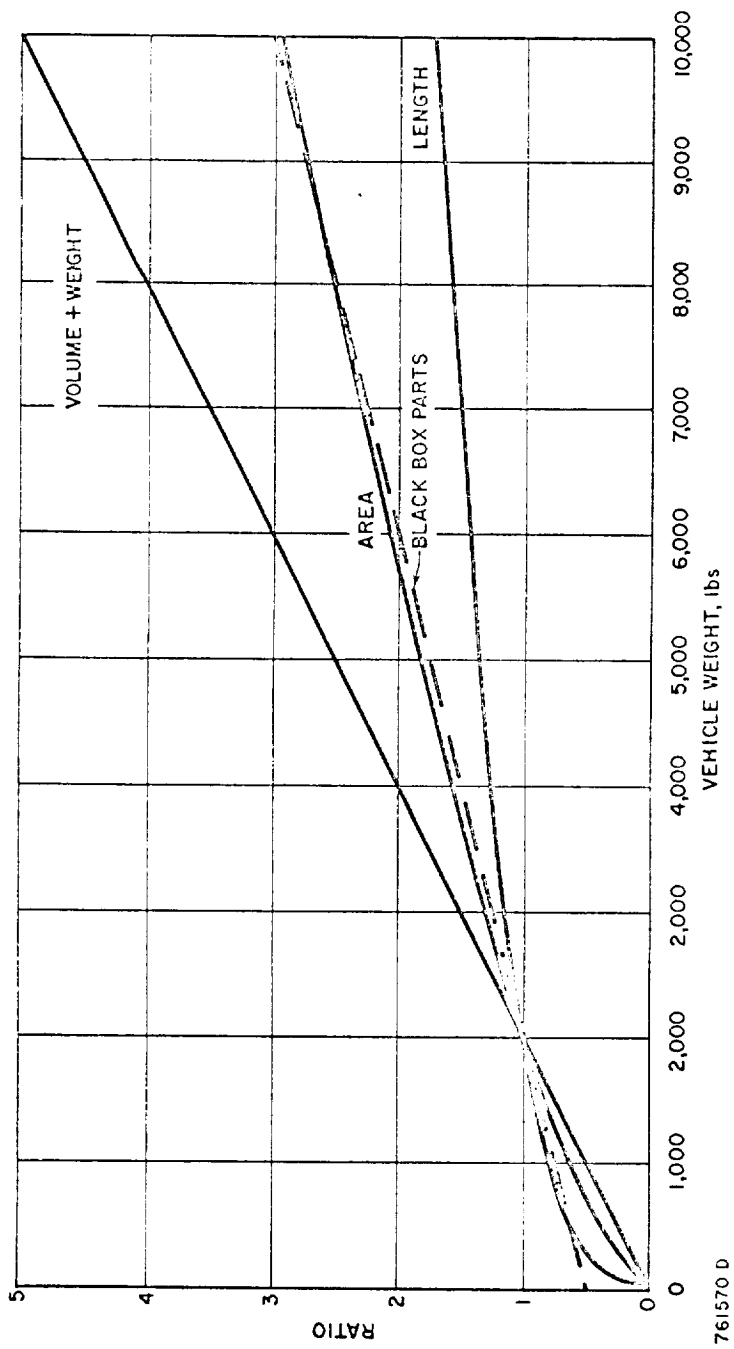


Figure 2 AERO MICROBIAL BURDEN PREDICTION RATIOS

In each run involving a vehicle other than 2,000 pound, the factors indicated in Figure 2 were considered to apply to each of their respective areas, thereby creating, for study purposes, a vehicle of the desired weight class. All calculations of burden, such as fallout, handling, etc., are kept constant in each case so that the effect of weight change, including the variables just discussed, can be seen as a separate parameter.

4.0 RESULTS AND CONCLUSIONS

Table III contains, for each of four weight classes of vehicles, complete identification and raw data results of all 54 computer runs. Although this follow-on study is principally concerned only with runs 23 through 54 for each weight class, and complete results will be discussed to avoid the need for considerable cross referencing. The results of this study are presented in two basic forms: The first is a set of curves showing biological burden versus vehicle weight under various conditions; the second is a set of nomograms that apply to each of eight possible control combinations studied. The curves first discussed, are, in turn, broken down into two types. Figures 3 through 8 account (for given control situations of burden versus vehicle weight) for various burden fallout, electrostatic-factor, die-off, and internal-burden conditions. Figures 9 through 27 show burden versus vehicle weight for single parameter variation.

Figure 3

This figure presents the data from runs 18 through 22 and 45 through 47. This set of eight runs is based on fallout, electrostatic factor, and die-off inputs of 32, 5, and 90 percent, respectively. Each run, however, calls for various combinations of ETO, clean-room, and flight-acceptance controls. For example, run 21, which indicates the highest burden, uses no controls; run 47, with the next highest burden, uses only clean room; etc.; the lowest burden being indicated in run 22, which uses all controls, ETO, clean room, and flight acceptance. This curve shows therefore the relative effect that varied controls, singly or combined, can have on the total burden, all other conditions in the assembly process being unchanged. It is interesting to note that the flight acceptance heat cycle alone is far more advantageous, in this case, than is a clean room alone and that ethylene oxide alone is superior in burden reduction than is a clean room alone. The most effective single control is the flight acceptance heat cycle, and the most effective set of two controls is clean room and flight acceptance cycle. The most effective set of controls is quite clearly the use of all three, which, in this case, yielded the lowest burden rates for each vehicle weight.

Figures 4 and 5

These figures show the effects of exercising various combinations of controls, all other conditions being the same and the mated area being considered nominal (or 17 percent) in the case of Figure 4 and 20 percent of nominal (or 3.4 percent) in Figure 5. In Figure 4, where the fallout rate is 128, the electrostatic factor 10, and the die-off 30 percent; we see that the most effective single control is the clean room. (Note that in Figure 3, the most effective single control is the flight acceptance cycle.) The most effective single control in this case is not the same as it is under lighter fallout and more normal die-off conditions, since the initial burden, killed by the flight acceptance cycle,

is greater than the burden accumulated during assembly. Therefore, under conditions of higher fallout, the use of a clean room becomes more significant than it does under conditions of lower fallout. Further, under these less favorable conditions, the use of a clean room becomes more significantly advantageous than it would be otherwise, and the usefulness of controls becomes significant, first for clean room, second for ethylene oxide and third for flight acceptance at the component level. As might be expected, run 42 shows that the best combination of two controls is the clean room-flight acceptance heat cycle; obviously, the most favorable control situation is the use of all three controls: ETO, clean room and flight acceptance. One interesting indication of these curves is that, though the clean-room control is a more effective single control than the flight acceptance heat cycle, the combination of ethylene oxide and flight acceptance heat cycle is more effective than the ethylene oxide-clean room combination. Since the flight acceptance cycle used initially is followed by ethylene oxide, more total burden is killed than if only the clean room and ETO cycles are used, reason being that although the flight acceptance heat cycle kills all of the internal and initial burden on the capsule elements the other controls affect only burden added during final assembly. Therefore, if only the ETO and clean-room controls are used, this initial burden remains and continues to be trapped between mating surfaces during final assembly. Obviously, the earlier application of a flight acceptance heat cycle eliminates this initial burden and thereby keeps the burden down between mating surfaces.

Figure 6

This figure is based on run 5, which was set up to indicate what the final biological burden of the vehicle would be under the most favorable circumstances: The run was set up to account for a fallout rate of 32 organisms per square inch per day under a normal environment, an electrostatic factor of only 1, and a die-off of 99 percent. In addition, ETO, a clean room, and the flight acceptance heat cycle were used. This curve indicates that with a 10,000-pound vehicle built under these conditions the total burden on the vehicle would be extremely low, not exceeding 10^6 total organisms. The principal reason for this very low number is the assumed high die-off of 99 percent and the assumption that all internal burdens are only 1/10 of expected normal. Conditions otherwise are close to what would actually be expected under normal conditions, therefore indicating that the low total burden is not an unreasonable estimate in terms of what might actually be expected.

Figure 7

This figure shows the burden estimates based on computer-run number 6, which was organized to show the highest possible burden on the vehicle, when all the controls available are used and all internal burdens are assumed ten times as large as expected. The fallout rate was therefore taken as an exceptionally high 128 organisms per square inch per day, the electrostatic factor as 10, and the die-off rate as only 30. These results indicate that even under the least favorable contamination conditions the use of the available controls will still keep the burdens down to 20 percent allowable, even on a 10,000-pound vehicle.

Figure 8

This figure is based on runs 7 and 8, which were made to identify variations in total burden as a function only of changes in the internal burden of nonmetallic parts. This burden involves, principally, that within the rocket motor fuel, the parachute, and the cabling. These runs were made on the basis of the highest fallout rate studied, the highest electrostatic factor and the lowest die-off. In addition, no controls were applied. The result of this approach is that the effect of internal burden changes may be seen without the complimenting effects of other controls or processes. While this approach is parametrically cleaner than it might otherwise be if controlling conditions were assumed, the burden rates generated are unrealistically high. In these runs, there is no intent to indicate burdens that might be encountered under normally controlled conditions. This figure shows that were the internal burden raised in magnitude the total uncontrolled burden of the vehicle would rise astronomically. On the other hand, if the internal burden is reduced one order of magnitude, from what was considered normal, the total burden of a 2,000-pound vehicle becomes approximately 46×10^8 organisms. This, as seen from Table I, is only slightly lower than the total burden of the 2,000-pound vehicle in run 1, in which the internal burden is normal and the other conditions of the run remain the same.

Figure 9

This figure is based on runs 1, 9, 10, and 11 and shows the burden versus vehicle weight as a function of change in fallout rates. Since no controls are used for any of these runs, the burdens are all quite high relative to the acceptable level of organisms. These data, nevertheless, indicate total-burden percentage reductions that may be expected with corresponding reductions in normal fallout rates. The curve indicates that when the fallout rate is reduced from 128 organisms per square inch per day to 32 organisms per square inch per day (a value of $1/4$ of the fallout), the total burden on the 2,000-pound vehicle falls from 49×10^8 organisms to a value of 21×10^8 organisms, or to less than $1/2$ as much.

Figure 10

This figure is based on runs 1, 12, 13, and 14 and shows the change in total burden as a function of electrostatic factor. It is evident (Figure 9) that changes in electrostatic factor are not as sensitive as changes in fallout rate. It is noteworthy, however, that for a 2,000-pound vehicle a change in electrostatic factor from 10 to 1 accounts for a reduction in total burden of nearly 20 percent. This is a significant reduction and is a function not only of the electrostatic factor itself but of the relative surface areas of non-metal parts. Therefore, to minimize the effect of electrostatic factor on total burden, it is not only important to minimize the use of large areas of non-metal in the design itself, but to control atmospheric conditions in the assembly operation so that electrostatic factors are minimized on whatever non-metal surfaces that do exist.

Figure 11

This figure is based on runs, 1, 15, 16, and 17, and shows the effect of changes in die-off rate of organisms on total vehicle burden. It is clear that of those factors

discussed so far this one shows the greatest sensitivity to any one parameter. On a 2,000-pound vehicle, for example, the burden with a 30-percent die-off is 49×10^8 organisms, while, were the die-off increased to 99 percent, all other conditions being unchanged, the burden would be only 10×10^8 organisms. This shows the critical importance of knowing and understanding the die-off kinetics of organisms that may be found on a capsule.

Figure 12

This figure is based on runs, 1, 23, 24, and 25 and shows how final burden is affected by variations in handling burden as the vehicle is carried through final assembly. The most obvious feature of this curve is the insignificant change in total burden, as a function of vehicle weight, when changes in handling burden are below 1900 organisms per square inch per contact. When the burden becomes as high as 19,000 organisms per square inch per contact, however, a significant change in the total burden of the vehicle begins to appear. This happens because the total area handled during final assembly is relatively small as compared to the total surface area of the vehicle. Consequently, it takes an extremely high handling burden to show a significant result in terms of total vehicle burden.

Figures 13 and 14

Figure 13, even though it contains only one line, is based on runs 1, 26, 27, and 28. The reason there is no variation in total burden, as a function of vehicle weight, with a change in mated area proportion is that as the mated area of the vehicle is reduced biological burden, which was considered as mated burden, becomes considered as surface burden. Thus, while the total burden remains the same, the ratio of surface to mated burden changes as biological burden is transferred from the mated category to the surface category. Figure 14, shows this effect in a slightly different manner, i. e., surface burden shown as a function of the mated area in terms of percent of original mated area. Here it is easy to note that as the percent of original mated area is reduced the amount of mated burden is reduced and, consequently, the amount of surface burden is increased. For these particular runs, no controls were used; had ethylene oxide been used, however, the burden transferred, as a function of reduction in mated area, to the surface category would have been reduced, reducing total burden. The conclusion follows that it is important to keep the mated area as small as possible to reduce the burden inaccessible to ethylene oxide.

Figure 15

This figure is based on runs 29, 30, 31, and 51. For each, the fallout rate is considered 128, the electrostatic factor 10, and the die-off rate 30. Also for each, ethylene oxide is not considered applicable and the assembly process is not considered to be carried out in a clean room. The only variation in these runs is the point at which the flight acceptance heat cycle is applied. (Definitions of these points are contained in Section 2 above.) It is evident that a delay in

the application of the flight acceptance heat cycle to some point down stream in the final assembly process results in a larger burden destruction than the application at component level only. These data then seem to reinforce the logic that a tradeoff is necessary between the need for applying the flight acceptance heat cycle at the point of maximum effectiveness and the risk of having to scrap a larger and more complicated subassembly should there be a failure resulting from that application. To the extent that additional burden is killed as a function of late application, it is clearly desirable to delay the heat cycle to a point as close to the actual terminal sterilization heat cycle as possible.

Figure 16

This figure shows the result of changes in the effectivity of the flight acceptance cycle. The curve is based on runs 32, 33, 34, and 41. Obviously only one line exists; for, although effectivity of the flight acceptance cycle is varied from 6 to 12 decades of kill capability, there is no significant change in the total burden of the vehicle. The indication is that for burden control a 6-decade flight acceptance heat kill is quite adequate and, in fact, is essentially as adequate as a 12-decade kill. Therefore, any requirement for acceptance heat cycles of a greater capability would have to be for some purpose other than sterilization, e. g., a 12-decade heat cycle to determine component reliability.

Figures 17 and 18

This figure shows the change in burden versus vehicle weight as a function of ethylene oxide effectivity. The curve is based on runs 1, 35, 36, and 37. Noteworthy on this curve is that data for runs 1, 36, and 37 coincide with ETO effectivities of 4, 6, and 8 decades, respectively. In run 35, the ETO effectivity is 2 decades, indicating that only when the effectivity of ethylene oxide falls in the neighborhood of 2 decades of kill is it possible to see, when the assembly is complete, an effect on the total burden of the vehicle. Figure 18, indicates the same thing in a different manner. In this curve, burden is plotted as a function of ETO effectivity. Here it is seen that total burden rise is significant only after the ETO effectivity degrades beyond 2 decades. These data clearly show that as long as ethylene oxide decontamination cycles are properly applied there need be no concern for ETO effect on total burden, unless the effectiveness of the cycle is in the neighborhood of 2 decades or less.

Figure 19

This figure shows burden versus vehicle weight as a function of variations of clean room quality, ranging from 0.5 decades to 2.0 decades. This curve is based on runs 38, 39, 40, and 43. The basic data, as indicated on the figure, are for a fallout rate of 128, an electrostatic factor of 10, and a die-off rate of 30 percent. The only control used is the clean room itself. This curve

demonstrates that the use of a clean room of almost any reasonable quality reduces significantly final burden. The use of a 0.5-decade clean room reduces the total burden to less than 50 percent of what it would be under normal conditions. Clean rooms of increasing quality reduce the burden further: a 2-decade clean room reduces the burden to only 20 percent of what it would be were a clean room not used. It should be noted, however, that while the clean room is an effective control it is not as effective a decontaminating agent as the flight acceptance heat cycle, except when fallout rates are so high as to be considered generally unreasonable.

Figure 20

This figure is the first in a series of eight showing the effects varying controls has on burden. Burden versus vehicle weight is shown as a function of no controls and as functions of variations in fallout rates, electrostatic factor, and die-off. From this figure, we see that as fallout rate and electrostatic factor are reduced, and die-off increased, the total burden of the vehicle decreases significantly. On the upper curve, where the fallout rate is 128, the electrostatic factor 10, and the die-off 30, the data represent one of the two basic cases from which most of the runs of this study depart. The lower curve, on which fallout rate is 32, electrostatic factor 5, and die-off 90 percent, shows a set of conditions (the record of two basic sets) considered to be more realistic in light of literature and empirical data. Therefore, from the standpoint of determining actual final burdens without ethylene oxide, clean-room, or flight acceptance controls, the lower curve is a more reasonably accurate indication than the upper, which represents an unrealistically poor set of conditions used only for parametric purposes.

Figure 21

This figure shows the effect of ethylene oxide control on the total burden, as a function of vehicle weight: (1) for fallout conditions of 128, an electrostatic factor of 10, and a die-off of 30; (2) for fallout of 32, an electrostatic factor of 5, and a die-off of 90. The figure shows that ethylene oxide has reduced burden substantially from that shown in Figure 20. Figure 21 also shows that, when the mated area is reduced to a fraction of its original value, the ethylene oxide kills the burden now considered to be on the surface and previously on the mated area.

Figure 22

In this figure, the contaminating conditions remain as before, but ethylene oxide as well as clean room controls are used. Here one can see a further reduction in the final burden of the vehicle, the final values being essentially the same for the high contaminating conditions, even though the mated area is reduced to 20 percent of its nominal value. The reason is that the lower fallout conditions in a clean room determine that the relative proportion of additional burden that

may be killed as a function of ethylene oxide is considerably less than it would have been under non-clean-room conditions. As a result, the potential effect of mated area changes is reduced.

Figure 23

With the use of all three controls, under the contamination conditions defined earlier, the lowest burden values are achieved. It is shown that the use of all three controls significantly reduces the burden below what it was when only ethylene oxide and clean-room controls were used. (Note that Figure 23 is drawn in terms of burden $\times 10^{-6}$ and not 10^{-8} .) It is clear that the additional burden reduction by the flight acceptance cycle is essentially the internal, and originally occluded, burden that the ethylene oxide and clean-room controls were unable to reduce.

Figure 24

This figure shows that, the flight acceptance cycle as a single control, differences in fallout, electrostatic factor, and die-off have a very significant impact on the total final burden of the vehicle. It is shown that application of the flight acceptance cycle kills the initial burden on all surfaces of the elements making up the capsule. This destroys a significant percentage of burden that would have otherwise stayed on the vehicle, increases the proportion of burden put on the vehicle during final assembly, and increases the sensitivity of the final values to changes in final assembly contamination conditions.

Figure 25

When both flight acceptance heat cycle as well as clean-room controls are used, the burden is reduced approximately two orders of magnitude.

This difference is constant because of the reduced fallout rate in a clean room.

Figure 26

When clean room is the only control exercised, a reduction in contaminating conditions results in a modest reduction in final burden levels. The reason is that only the fallout conditions are controlled as a function of the clean room, and none of the burden on the vehicle is killed, either by ethylene oxide or flight acceptance heating, which would, respectively, reduce surface burden and essentially eliminate the internal and initial burden.

Figure 27

When a clean room is not used, but ethylene oxide and flight acceptance heat cycle are, the burden values resulting on the capsule are lower than they would

be had only a clean room been used. It is also interesting that for the high fallout case, where the mated area is only 20 percent of nominal, and additional amount of burden is killed by ethylene oxide, bringing the total burden value to a point nearly as low as for the normal fallout conditions.

Figure 28 *

Figure 28 is the first of eight nomograms developed to evaluate, simply and quickly, the sensitivity of the total burden on a vehicle to variations in one or more of several parameters. This figure, for example, is concerned with the control situation in which it is assumed that no ethylene oxide, no clean room, and no flight acceptance heat have been applied. The remaining nomograms present different control situations, each will be discussed in turn, but more consideration will be given to the no-controls situation so that its operation may be understood and its capabilities realized.

This and the following nomograms are operated by drawing straight lines between two sets of data, thus generating a point on a third line, this in turn either generating a new starting point or a result, certain conditions having been assumed.

Case Example, Figure 28

The assumption is that fallout is 128 organisms per square inch per day, the electrostatic factor is 10, and the die-off is 30. In Figure 28, a straight line is drawn from a fallout of 128 to an electrostatic factor of 10, thus generating a point on the vertical line between electrostatic factor and die-off. From this point, another straight line is drawn through a die-off of 30, this line intersecting the next vertical line. The point thus generated indicates that 49×10^8 organisms is the total burden on the vehicle under the conditions assumed. Table III shows that this operation on the nomogram has, for the 2,000-pound vehicle, effectively repeated the conditions of run number 1.

Should it be desired to examine the effect of variations in handling contamination, a straight line can be drawn from the last point generated through an assumed handling contamination rate to the next vertical line. Note that should this straight line be drawn through 1900 the value generated on the next vertical line remains at 49×10^8 . The reason is that in the initial study a handling contamination of 1900 organisms per square inch per contact was assumed for all the basic calculations; handling contamination variations, therefore, are treated as departures from 1900. Note that the straight line drawn from 49 through a handling of either 190 or 19 organisms per square inch per contact results in a burden of about 47.5×10^8 . This agrees with runs 23 and 24 in Table III, in which the burden for a 2,000-pound vehicle was computed to be 47.6×10^8 and 47.7×10^8 , respectively. Were the assumed handling burden on the high side, or 19000 organisms per square inch per contact, the resulting burden would be

*(For utility, the nomograms - Figures 28 to 35 - are enclosed unbound.)

61.5 x 10⁸ organisms, which agrees with run 25, in which the computed burden was actually 61.6. From this portion of the nomogram, it is possible to determine the effects of handling variations ranging from essentially 0 to 20,000 organisms per square inch per contact, indeed any set of assumed contamination conditions falling within the range of the nomogram. The next section of the nomogram is concerned with clean-room quality. Since this nomogram is based on the assumption that no clean room is used, it should be noted that a straight line drawn between vertical scales through the point identifying no clean room reads the same on both scales. For example, the straight line drawn from 49 x 10⁸ organisms through the "none" point also yields 49 x 10⁸ organisms. A point drawn from 49 through a clean-room point of 0.5 decades, however, generates a burden of about 22 x 10⁸ organisms. Table III, run 38, shows that the computer analysis of these same conditions yields a burden of 22.1 x 10⁸ organisms. The effect of clean-room qualities ranging up to 2.0 decades may be evaluated using this portion of the nomogram.

The next section of the nomogram is concerned with vehicle weight. Since all initial computer runs and calculations were made based on a nominal vehicle weight of 2,000 pounds, a straight line drawn from any burden value through a weight of 2,000 pounds will generate the same burden on the right-hand scale. Should one wish to depart from the 2,000-pound weight vehicle, however, and evaluate the burden on vehicles in the 1,000-, 4,000-, or 10,000-pounds, class a straight line drawn from any burden through the desired weight would yield the resulting change in burdens. For example, in the basic case, where the burden was found to be 49 x 10⁸ organisms, a line drawn through the 2,000-pound point would again generate a burden of 49. Should it be wished to see what the burden would be on a 1,000-pound vehicle, all other conditions being unchanged, a straight line drawn from 49 through the 1,000-pound point yields a burden of approximately 30 x 10⁸ organisms. This set of conditions coincides with run number 1 for the 1,000-pound vehicle, and the computer burden estimate is 31.1 x 10⁸ organisms.

With a basic understanding of these nomograms, it is possible to evaluate various tradeoffs yielding the same total burden. For example, were a highest handling contamination of 19,000 assumed, it would be quite simple to determine that level of clean room required to keep the burden at the same level it would have been had the handling contamination been lower. It is also possible to work backwards and determine what tradeoff conditions exist among fallout, electrostatic factor, and die-off to yield the same total burden. It is evident that under different fallout conditions, the electrostatic factor and die-off vary quite considerably in their sensitivity to the final burden value. Under high fallout conditions, for example, electrostatic factor is found to be quite sensitive, as is die-off. Under low fallout conditions, however, electrostatic factor and die-off are far less sensitive.

The nomograms in Figures 28 through 35 were developed from the data contained in the 216 runs, the results of which are contained in Table III. To the extent that

each of these runs can be traced on a nomogram, the nomograms are accurate; since examination of cases using random assumptions involves only interpolation and not extrapolation, the accuracy of the nomograms for any given situation is essentially as good as the accuracy with which the lines are drawn.

Figure 29

This nomogram operates exactly the same as that of Figure 28, except that this nomogram is based on the application of ethylene oxide, as described earlier. Therefore, any burden value generated on this nomogram assumes the use of ethylene oxide. Obviously, the values at any point on the figure are lower than those in the previous figure, as a function of the effect of the nominal ETO decontamination capability.

Figure 30

This nomogram is based on the use both of ethylene oxide and a clean room. The figure shows that a clean room plus ethylene oxide results in lower burden values, at any given point, than the values shown in the previous figure for ethylene oxide.

Figure 31

This nomogram is based on the use of all three controls: ethylene oxide, clean room, and flight acceptance heat cycle. The burden values on the vehicle are all quite small in relation to the values in previous nomograms. This is due to the decontaminating effect of the flight acceptance heat cycle. In no case does the burden approach 10^8 viable organisms. Even on a vehicle of 10,000 pounds, worst conditions assumed throughout the nomogram, the total burden on the vehicle prior to sterilization is not likely to exceed 0.25×10^8 viable organisms.

Figure 32

This nomogram considers only the flight acceptance heat cycle as a control. Note that, for high rates of die-off and low fallout and electrostatic-factor conditions, the burden on the vehicle can approach 0. The reason is that the acceptance heat cycle destroys internal, occluded, and initial burden that is on the capsule elements prior to final assembly. The burden values in this nomogram are therefore only those accrued during final assembly.

Figure 33

This nomogram considers the use both of clean-room and flight acceptance heat cycle but not of ethylene oxide. As shown, a clean room in addition to the flight acceptance cycle keeps the burden quite low; in fact, two controls approach the burden level achieved using all three controls.

Figure 34

This nomogram considers the use of a clean room alone. Note that the minimum burden of the vehicle, even with 100-percent die-off, is in the order of 8×10^8 viable organisms. This rather large burden is principally internal burden, contained by the rocket fuel, cabling, harnessing, and the main and pilot parachutes.

Figure 35

The final nomogram considers the application both of ethylene oxide and flight acceptance controls but not the use of a clean room. The minimum burden is quite low, since the flight acceptance heat cycle destroys initial and internal burdens and the ethylene oxide essentially decontaminates all the surface burden. This nomogram shows that a clean room may be desirable from certain stand-points but that it is not necessary for keeping the burden of a vehicle below 10^8 viable organism prior to the terminal sterilization cycle.

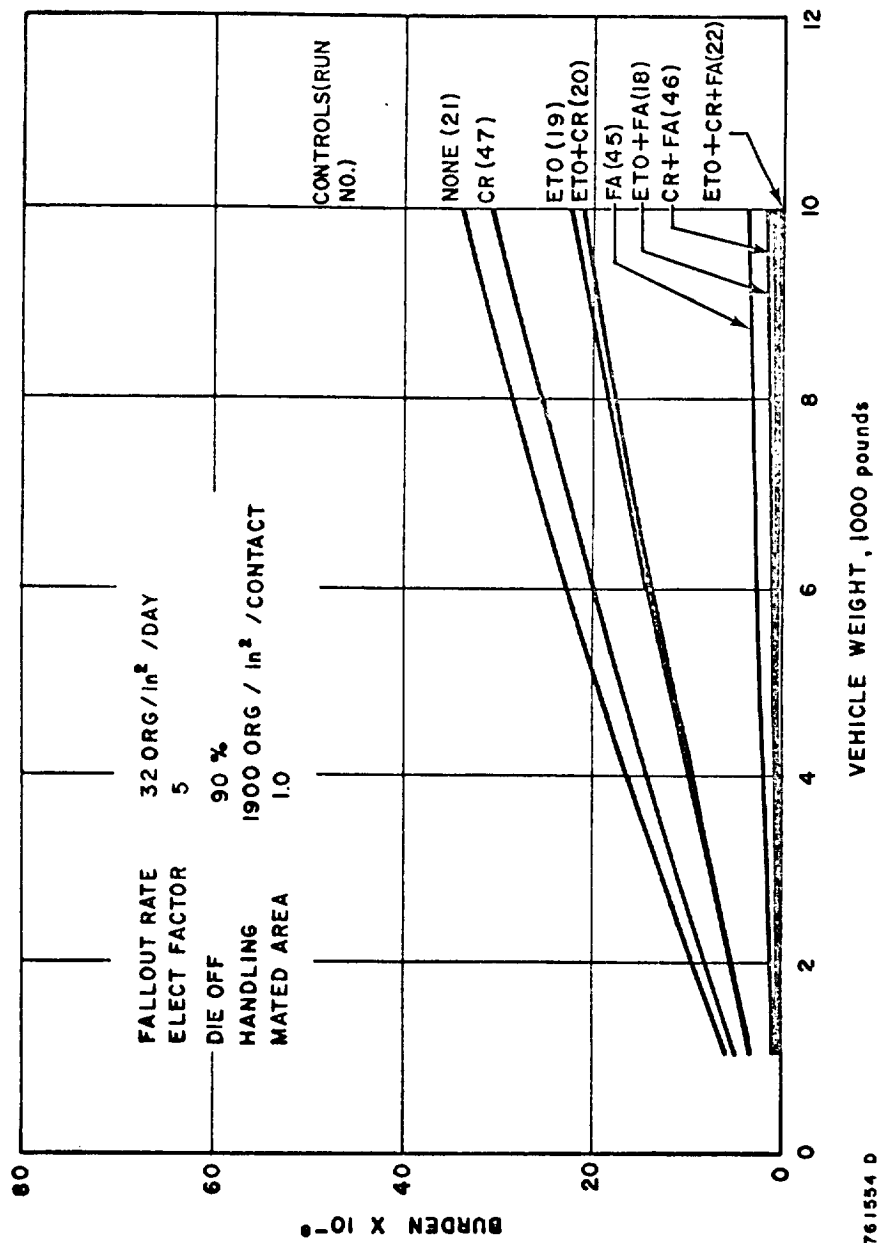


Figure 3 BURDEN VERSUS VEHICLE WEIGHT: CONTROL VARIATION FOR NORMAL ENVIRONMENT

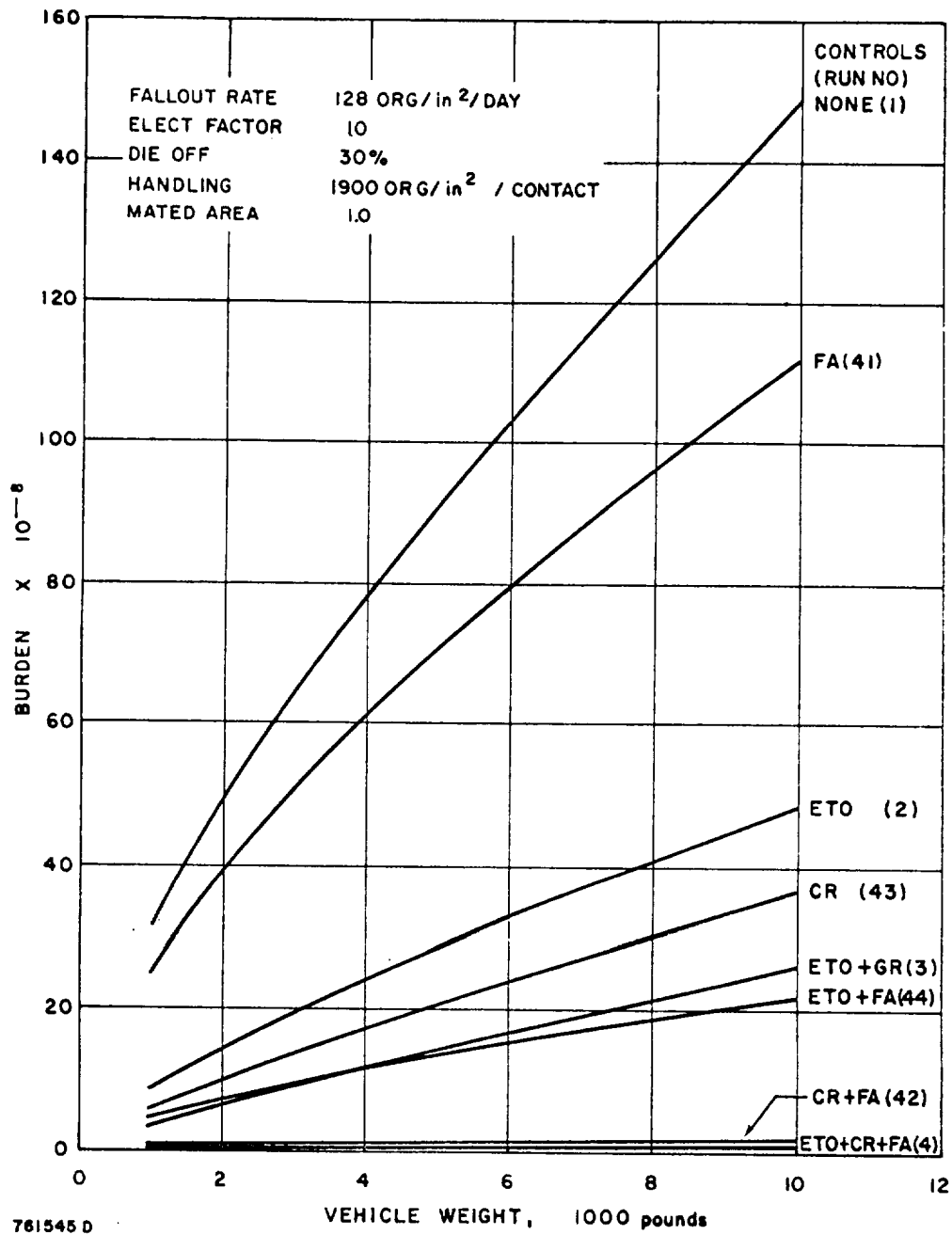


Figure 4 BURDEN VERSUS VEHICLE WEIGHT: CONTROL VARIATION FOR HIGH FALLOUT ENVIRONMENT (17 PERCENT MATED AREA)

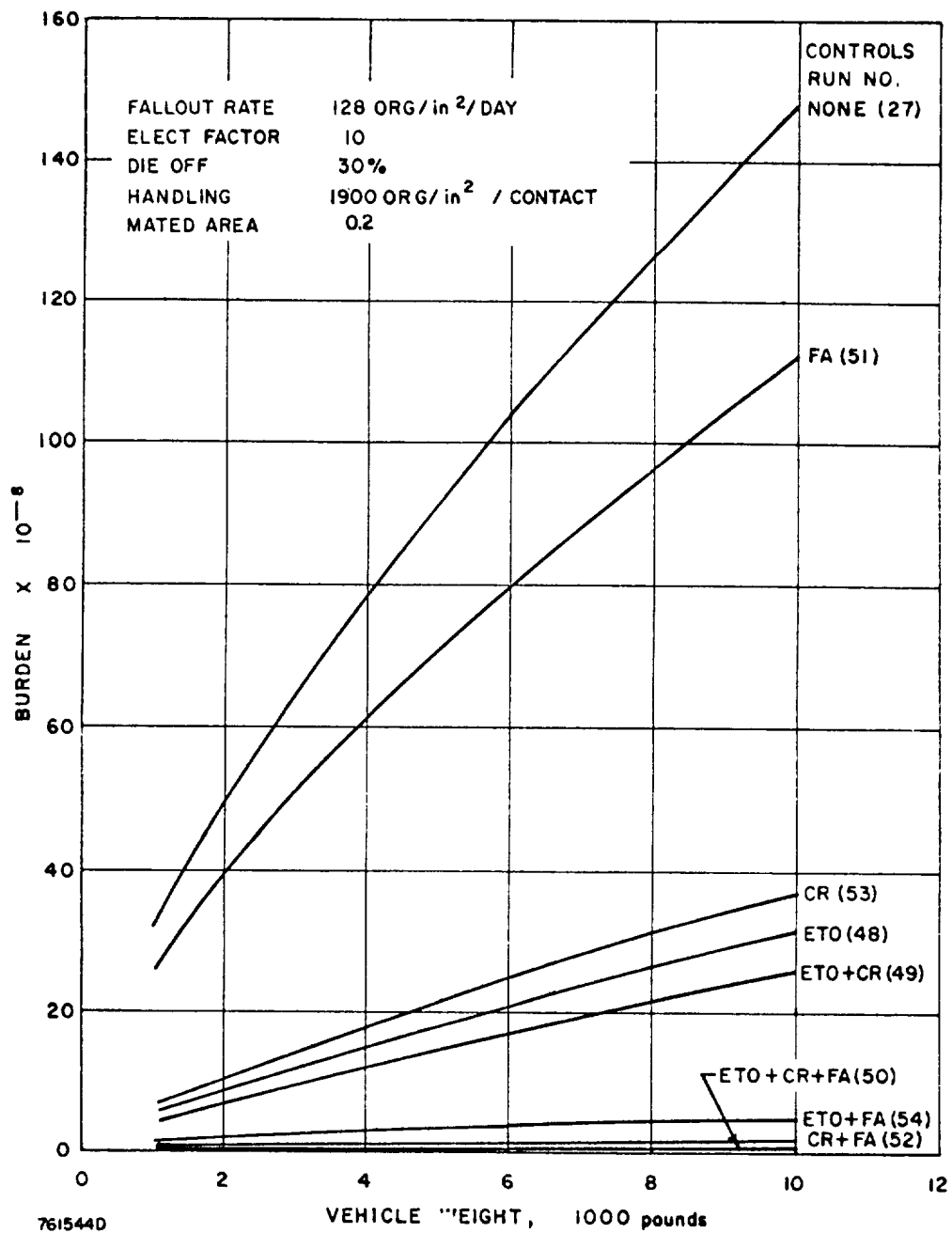


Figure 5 BURDEN VERSUS VEHICLE WEIGHT: CONTROL VARIATION FOR HIGH FALLOUT ENVIRONMENT (3.4 PERCENT MATED AREA)

BURDEN VS VEHICLE WEIGHT LOWEST CONTROLLED (-OM)

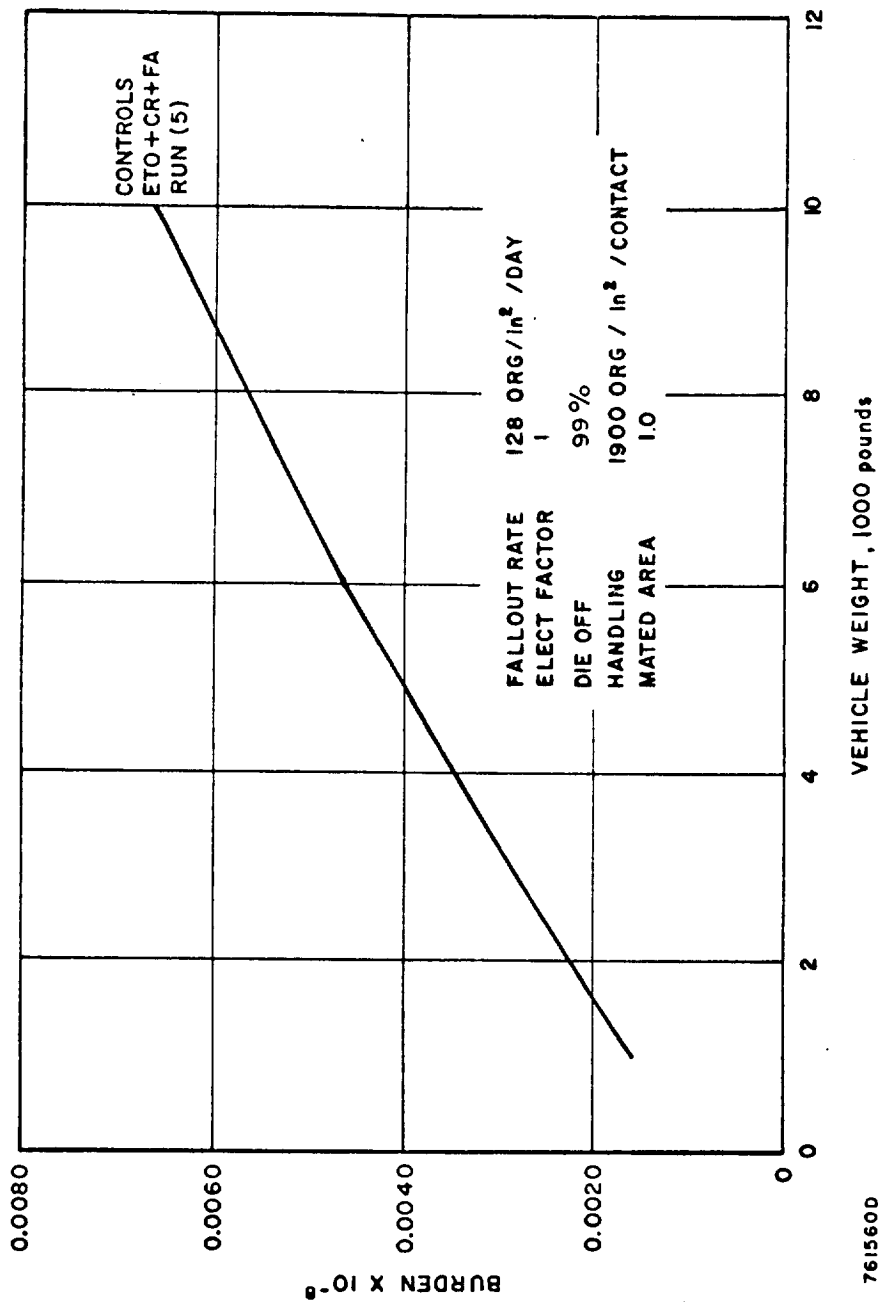


Figure 6 BURDEN VERSUS VEHICLE WEIGHT: LOWEST CONTROLLED BURDEN

BURDEN VS VEHICLE WEIGHT

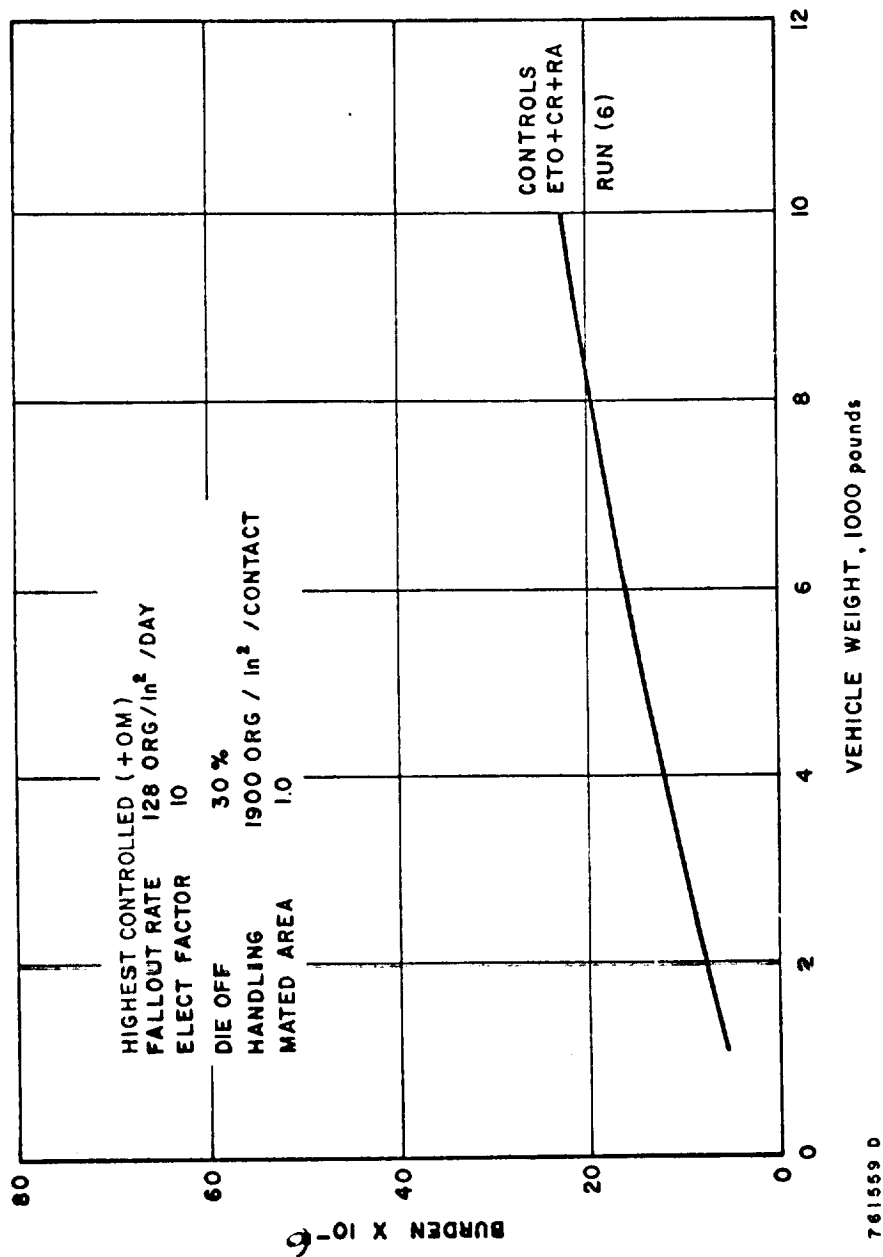


Figure 7 BURDEN VERSUS VEHICLE WEIGHT: HIGHEST CONTROLLED BURDEN

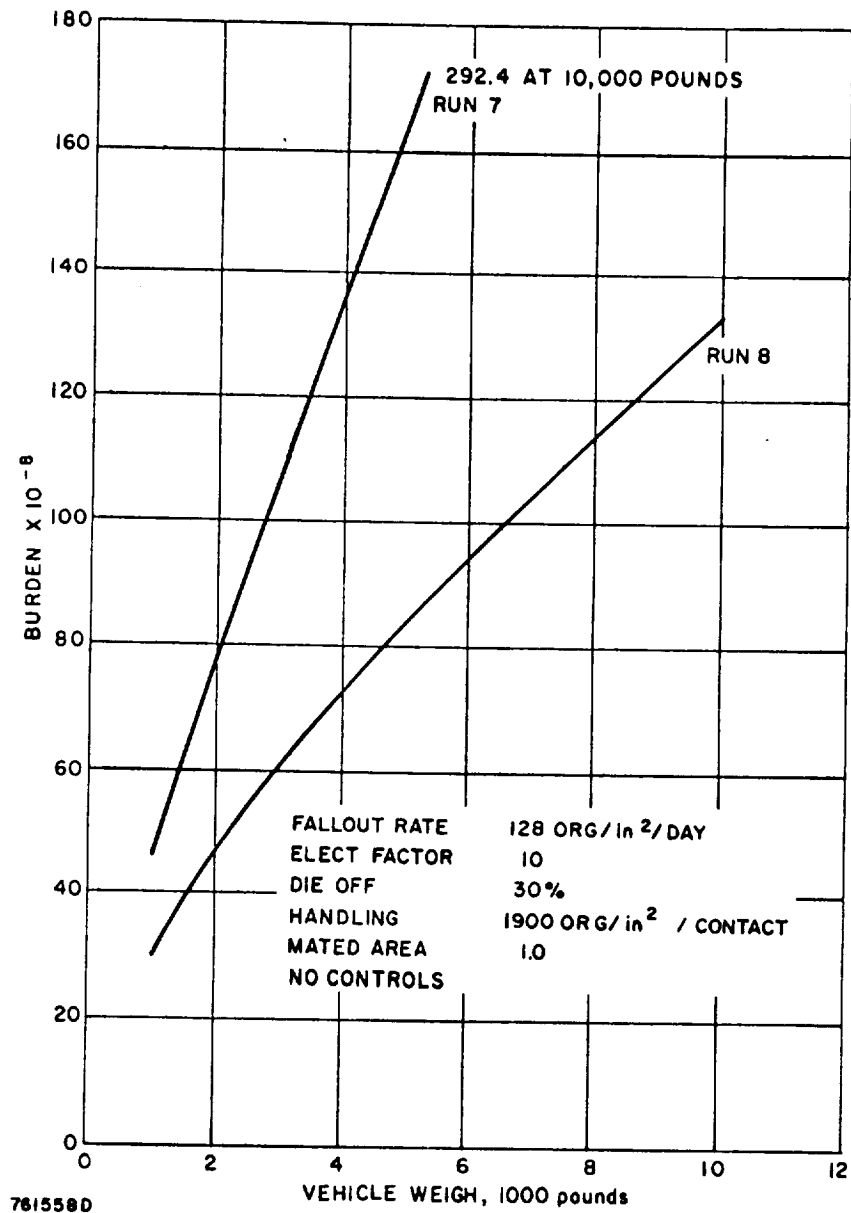


Figure 8 BURDEN VERSUS VEHICLE WEIGHT: INTERNAL BURDEN VARIATION

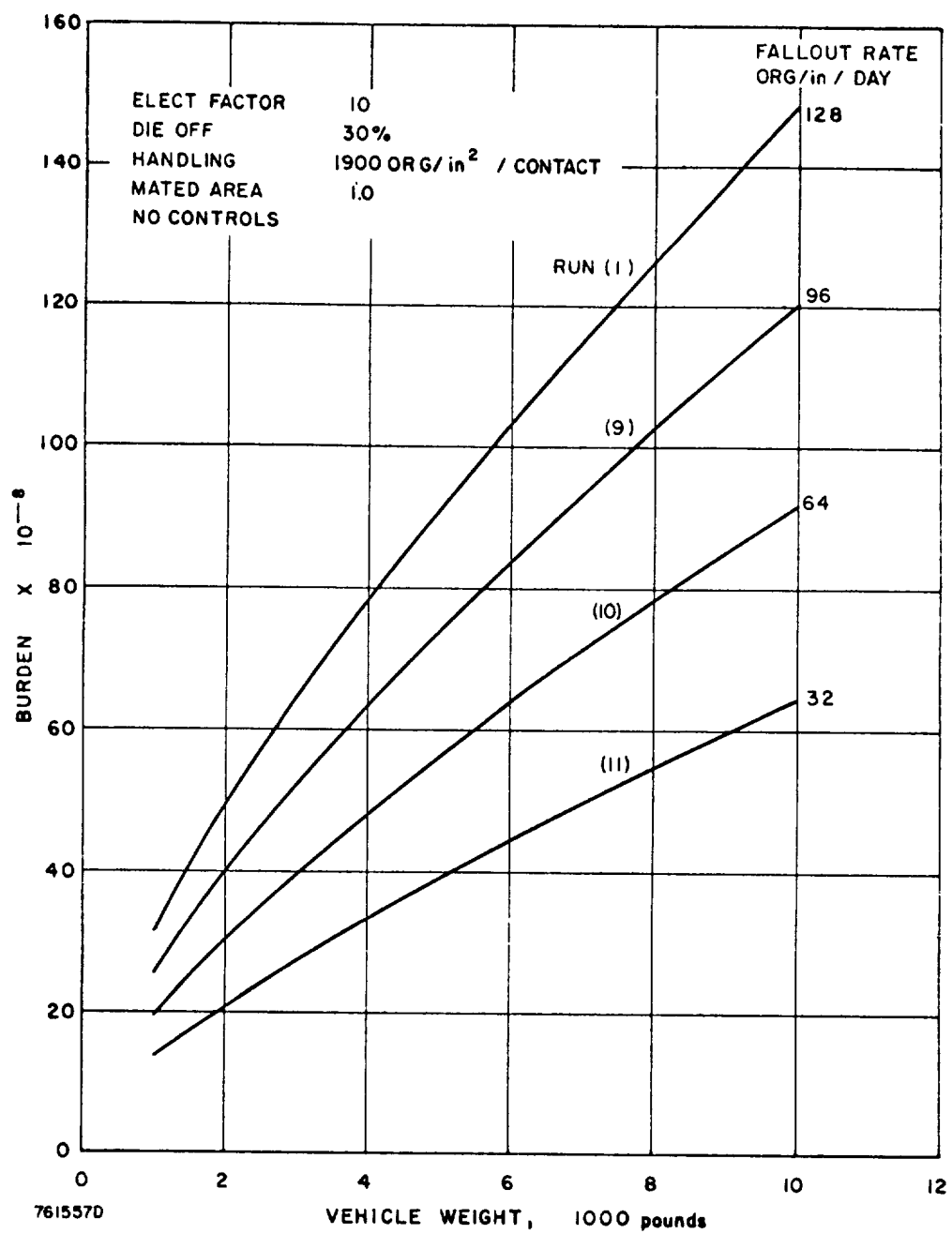


Figure 9 BURDEN VERSUS VEHICLE WEIGHT: FALLOUT VARIATION

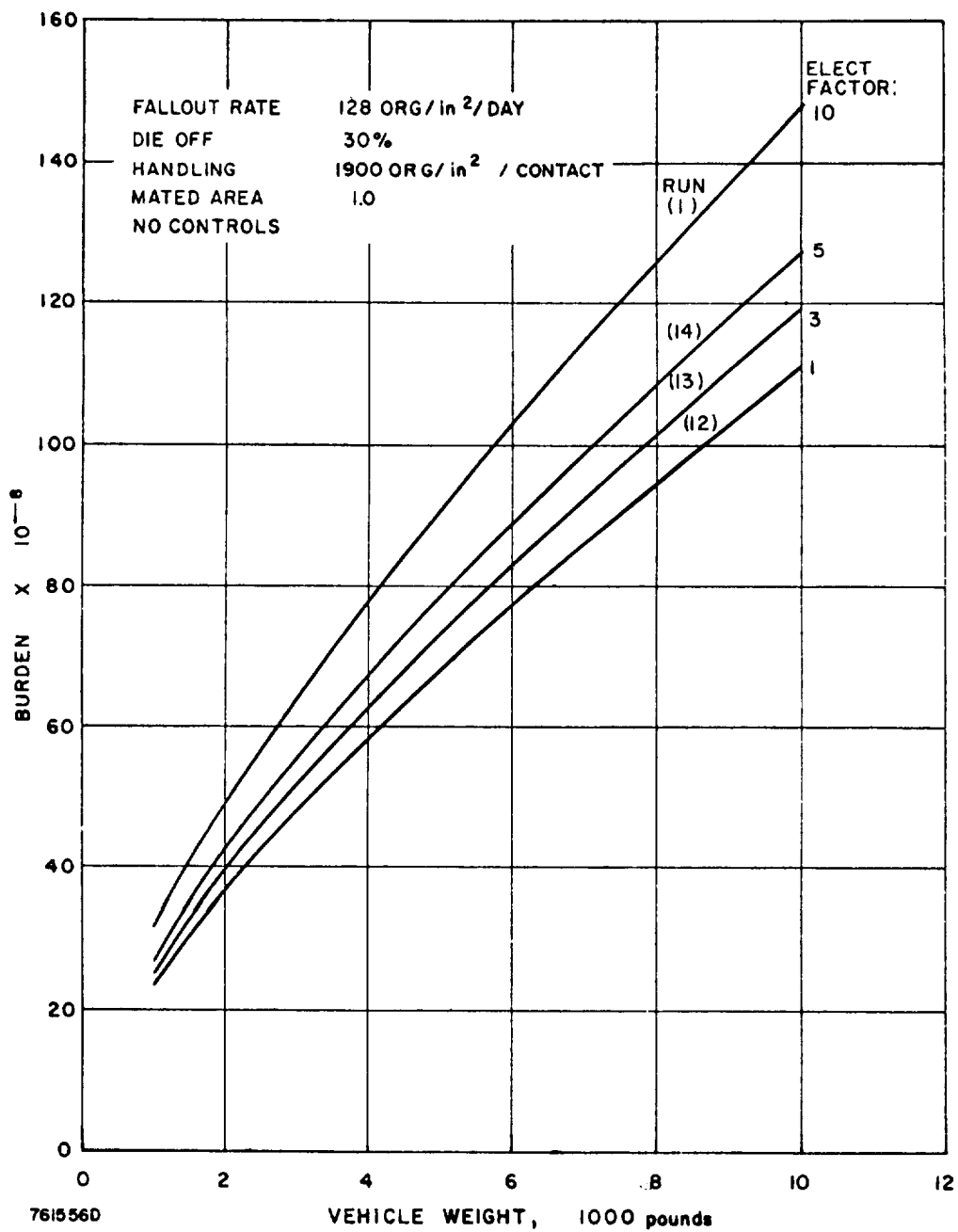


Figure 10 BURDEN VERSUS VEHICLE WEIGHT: ELECTROSTATIC FACTOR VARIATION

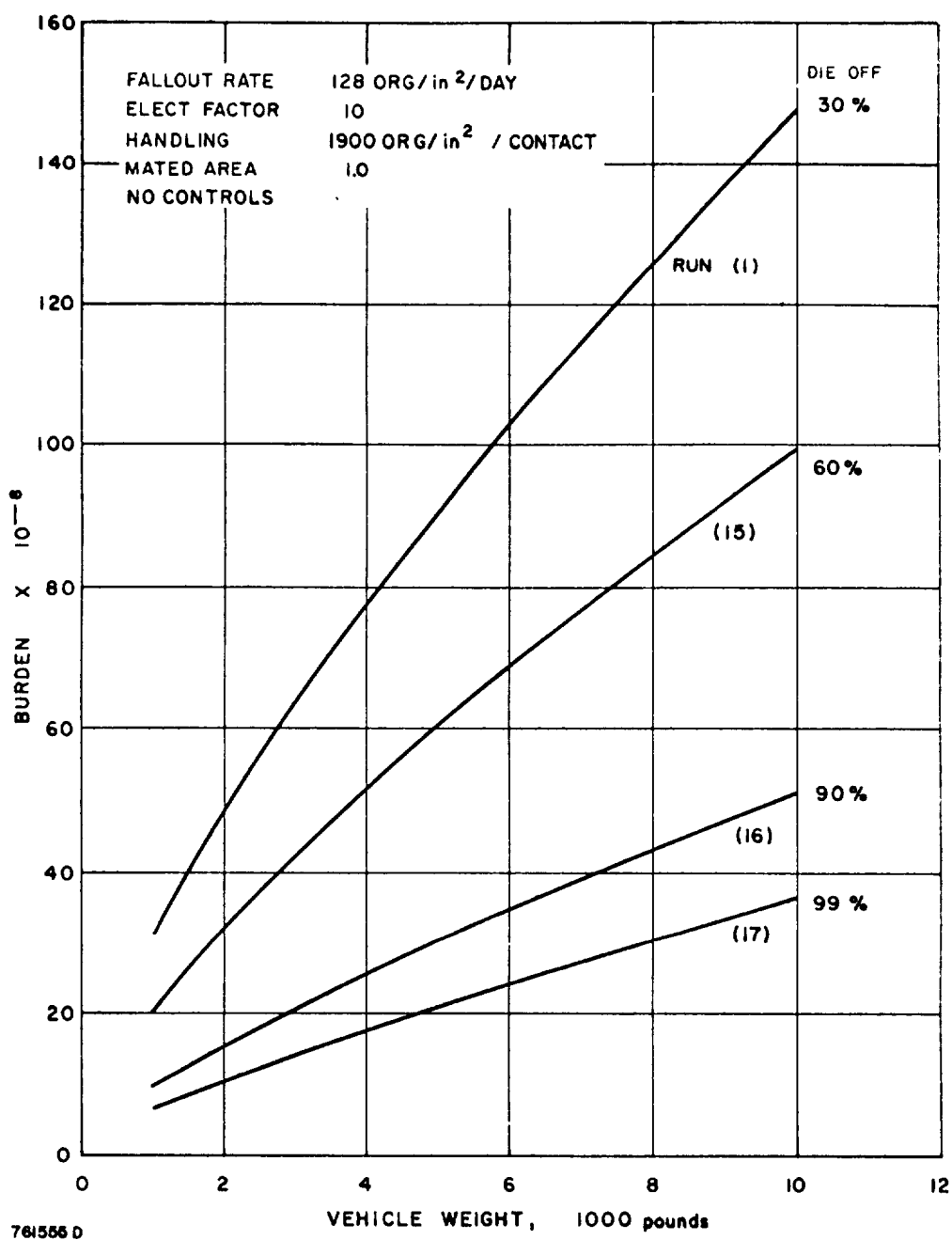


Figure 11 BURDEN VERSUS VEHICLE WEIGHT: DIE-OFF VARIATIONS

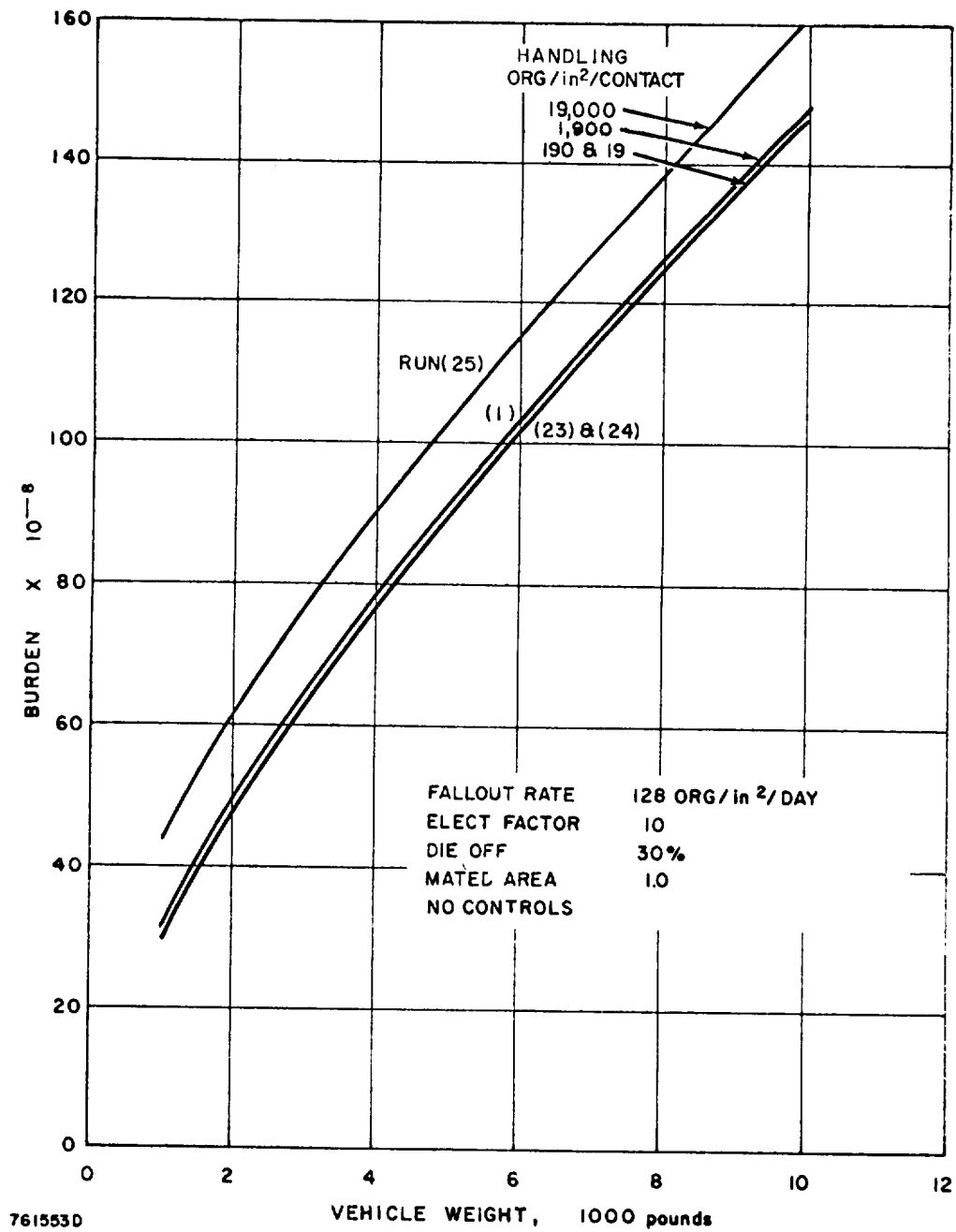


Figure 12 BURDEN VERSUS VEHICLE WEIGHT: HANDLING VARIATION

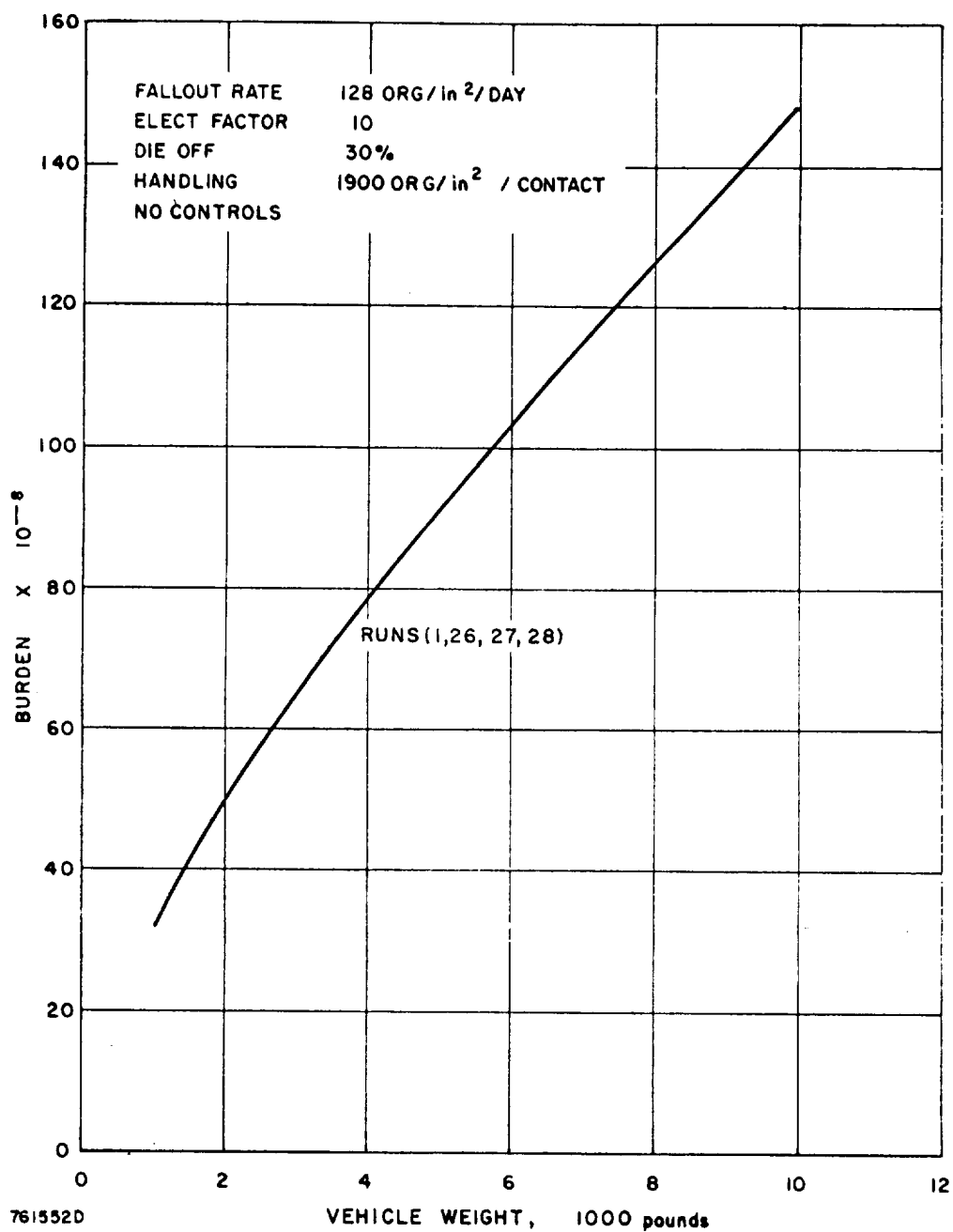


Figure 13 BURDEN VERSUS VEHICLE WEIGHT: MATED AREA VARIATION

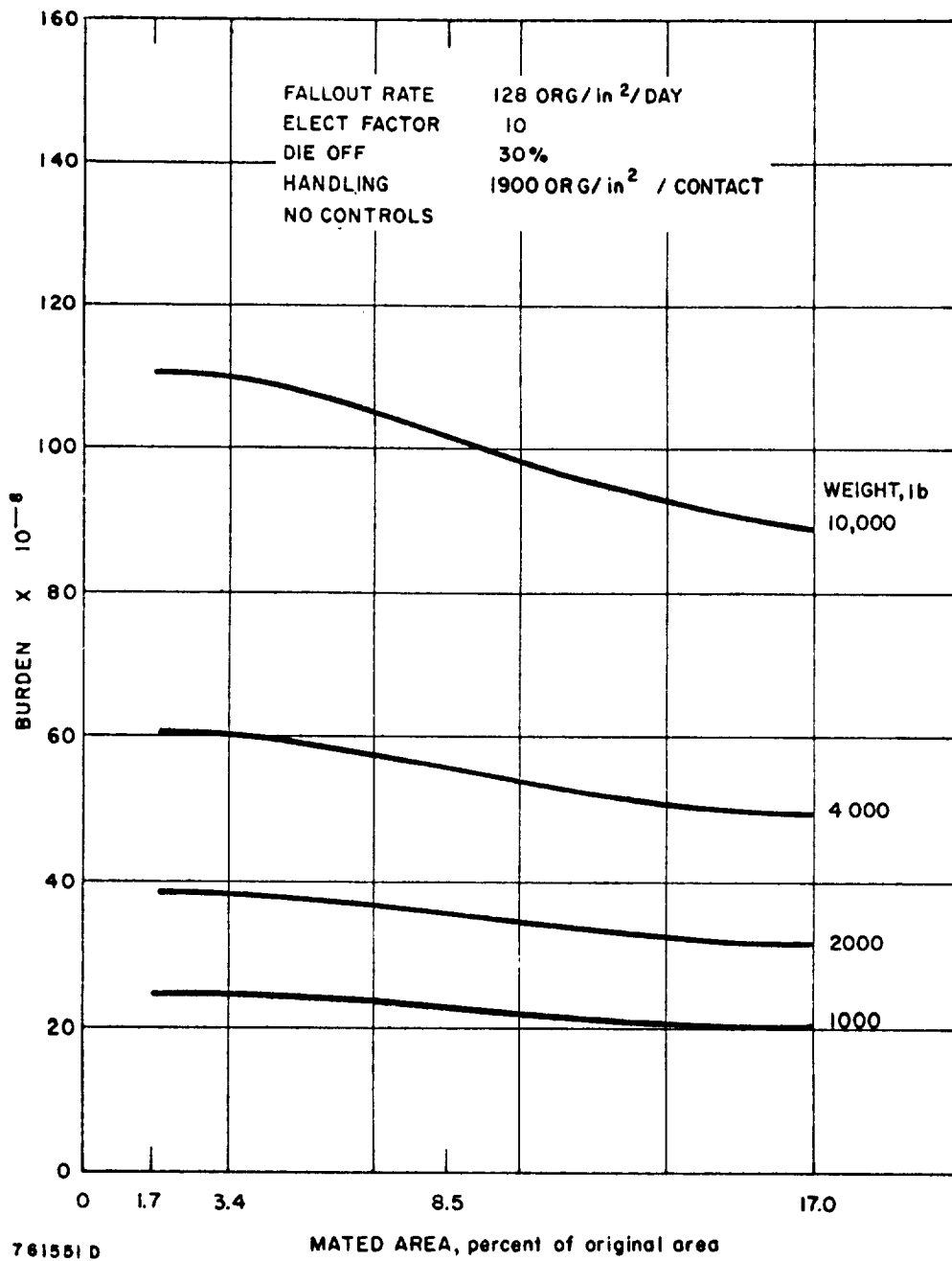


Figure 14 EXTERNAL BURDEN VERSUS MATED AREA

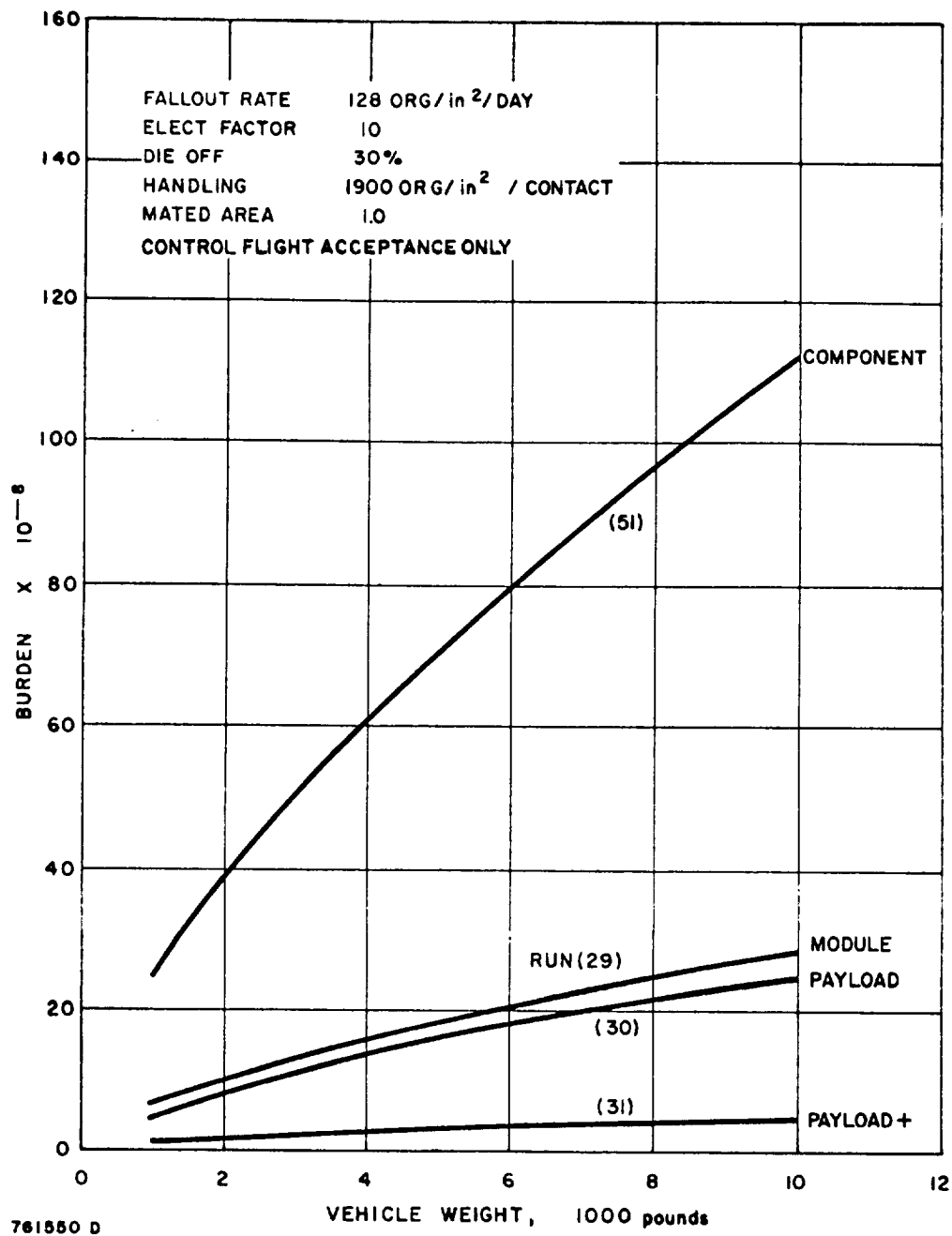


Figure 15 BURDEN VERSUS VEHICLE WEIGHT: FLIGHT ACCEPTANCE APPLICATION VARIATION

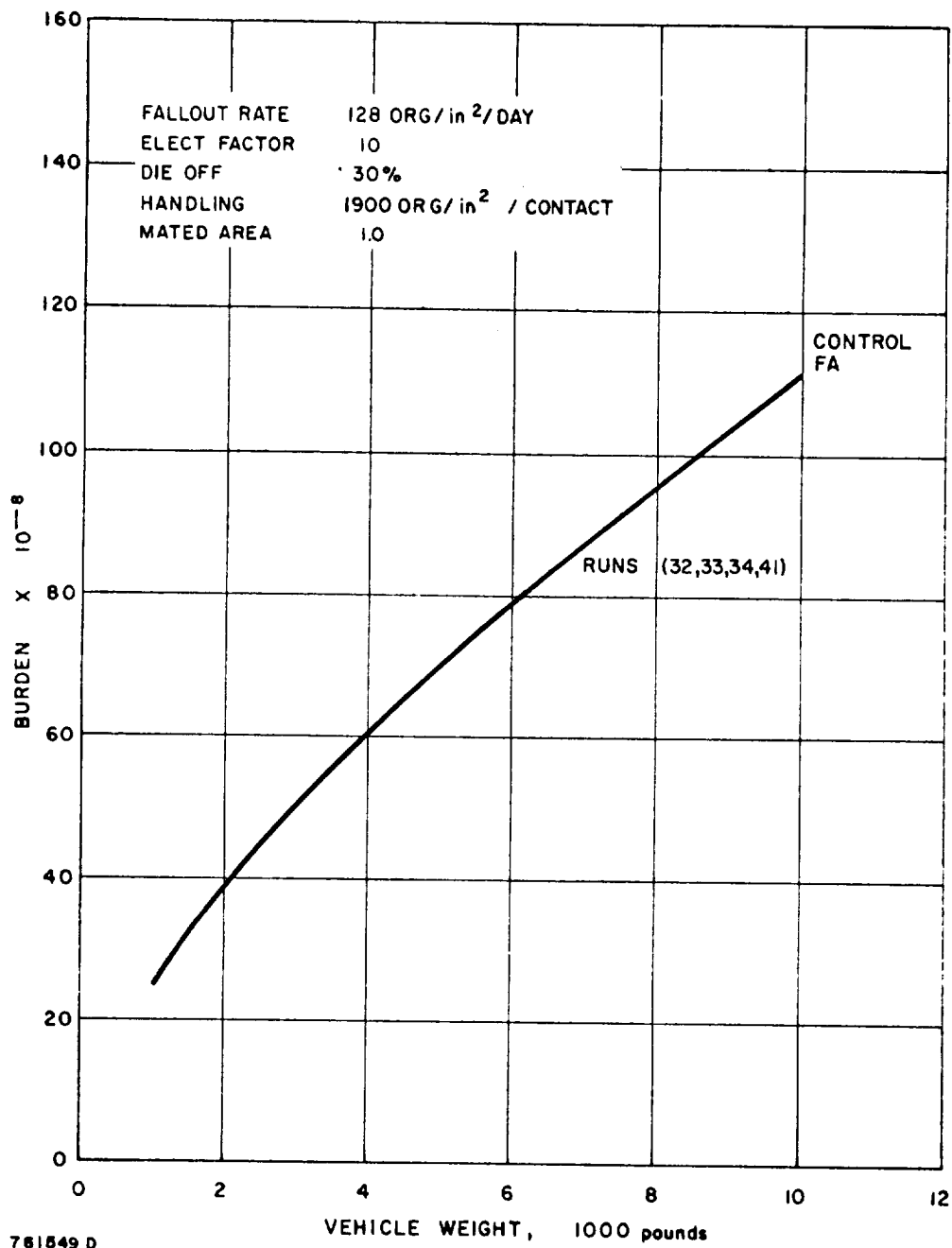


Figure 16 BURDEN VERSUS VEHICLE WEIGHT: FLIGHT ACCEPTANCE EFFECTIVITY

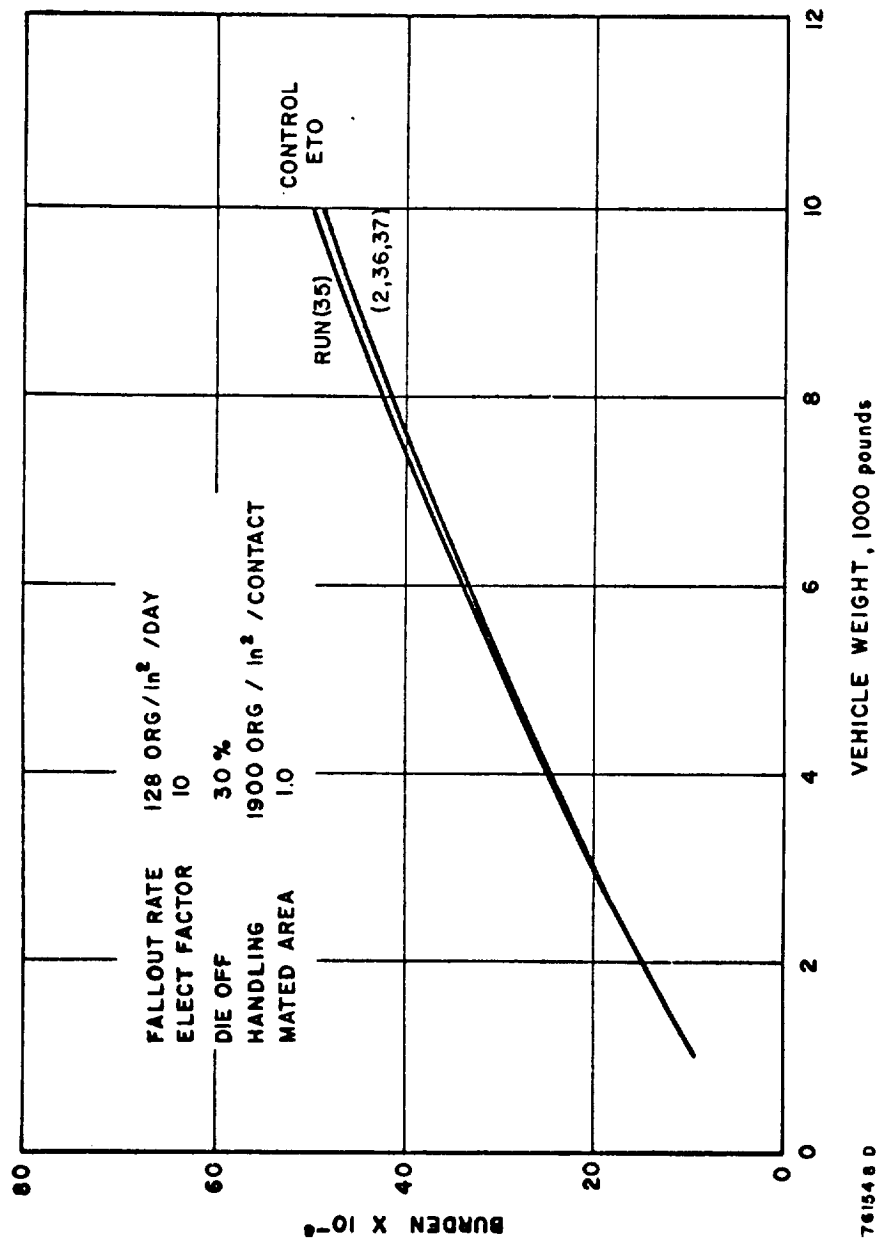


Figure 17 BURDEN VERSUS VEHICLE WEIGHT: ETO EFFECTIVITY

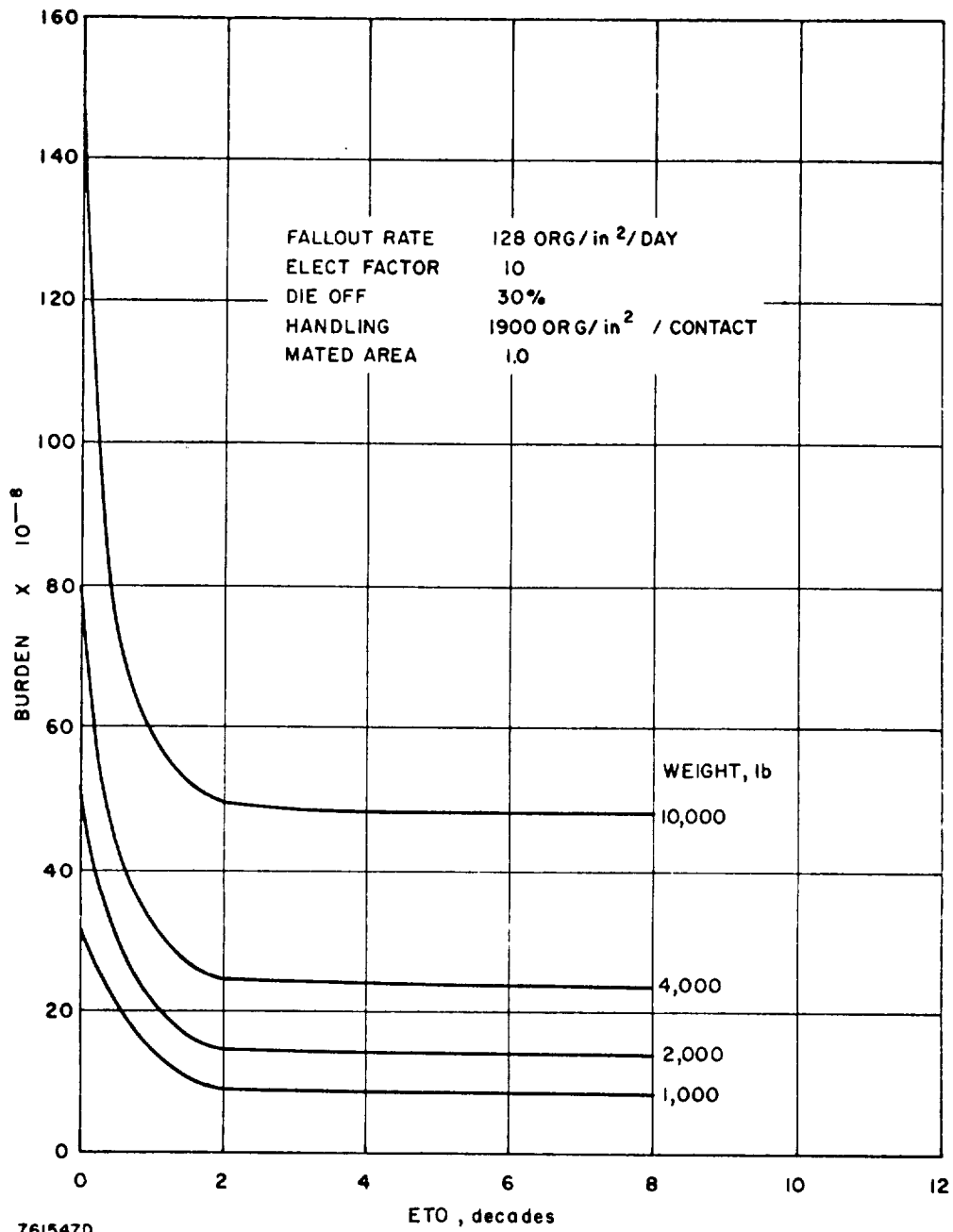


Figure 18 BURDEN VERSUS ETO EFFECTIVITY

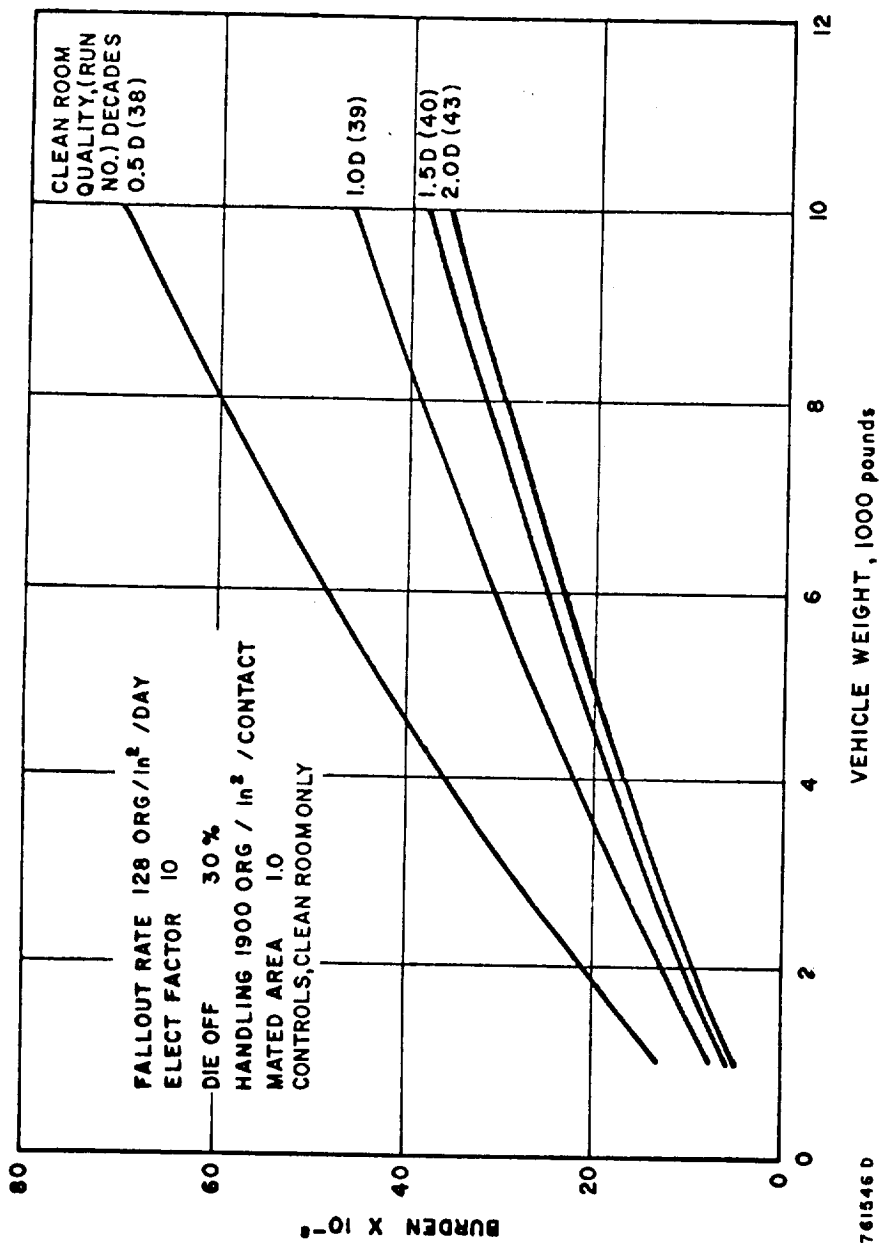


Figure 19 BURDEN VERSUS VEHICLE WEIGHT: CLEAN ROOM VARIATION

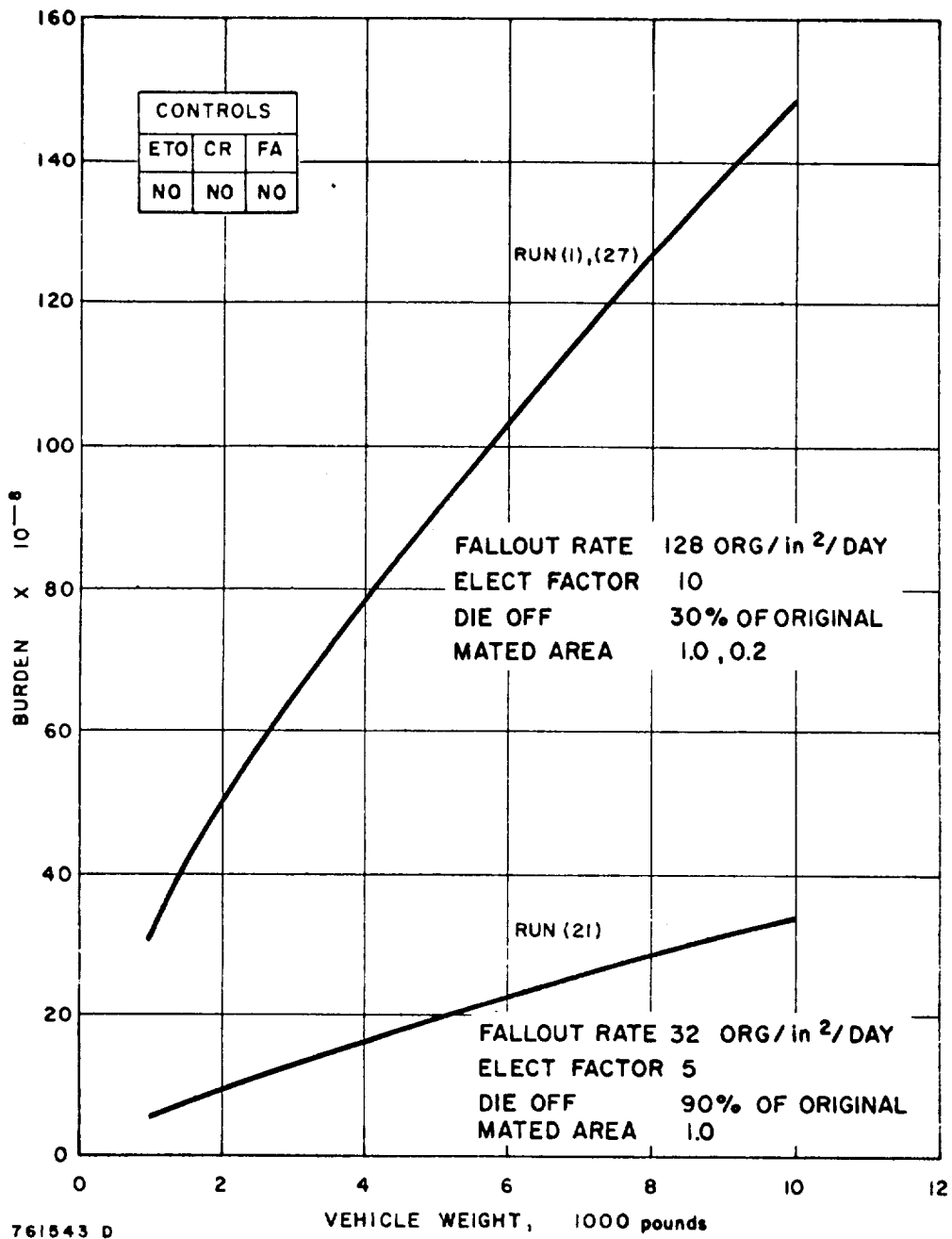


Figure 20 BURDEN VERSUS VEHICLE WEIGHT: NO CONTROLS

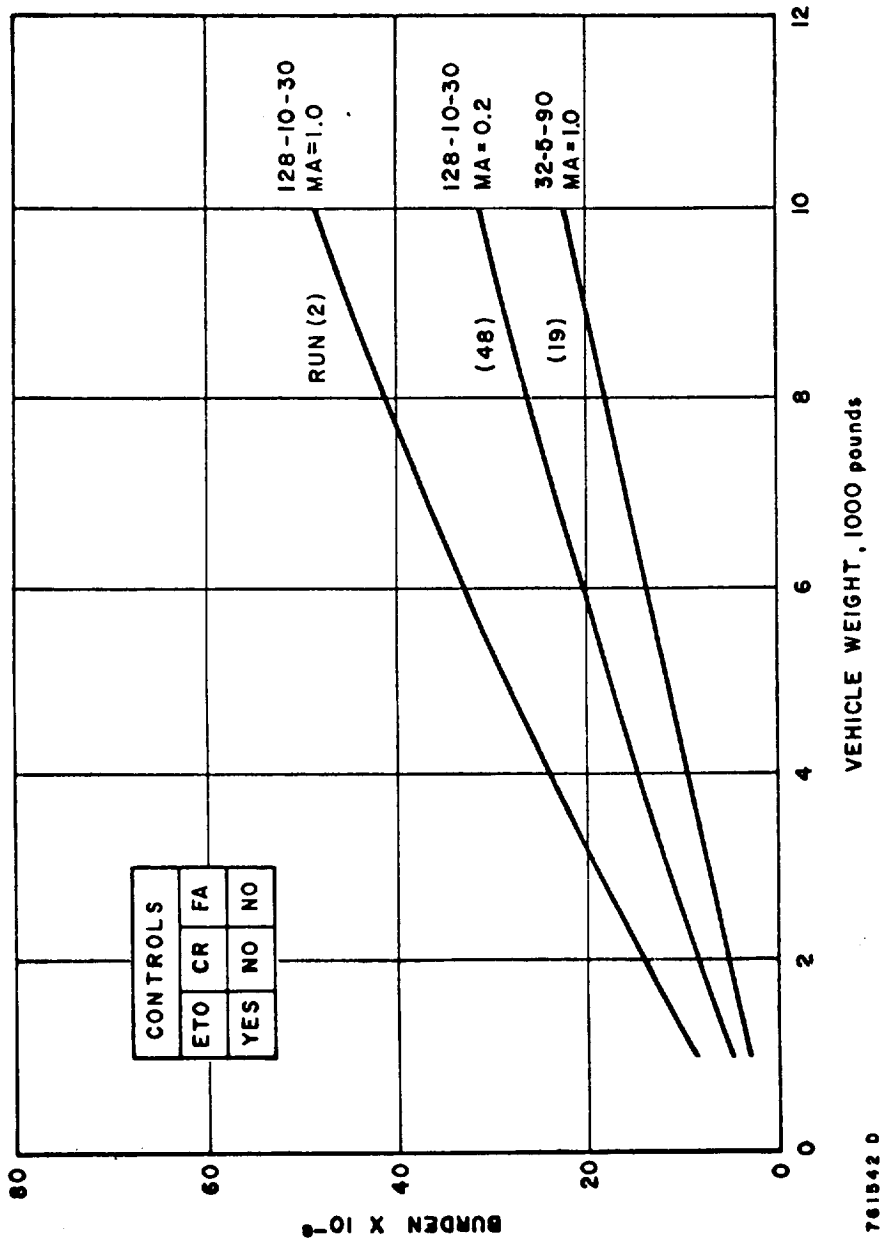


Figure 21 BURDEN VERSUS VEHICLE WEIGHT: ETO ONLY

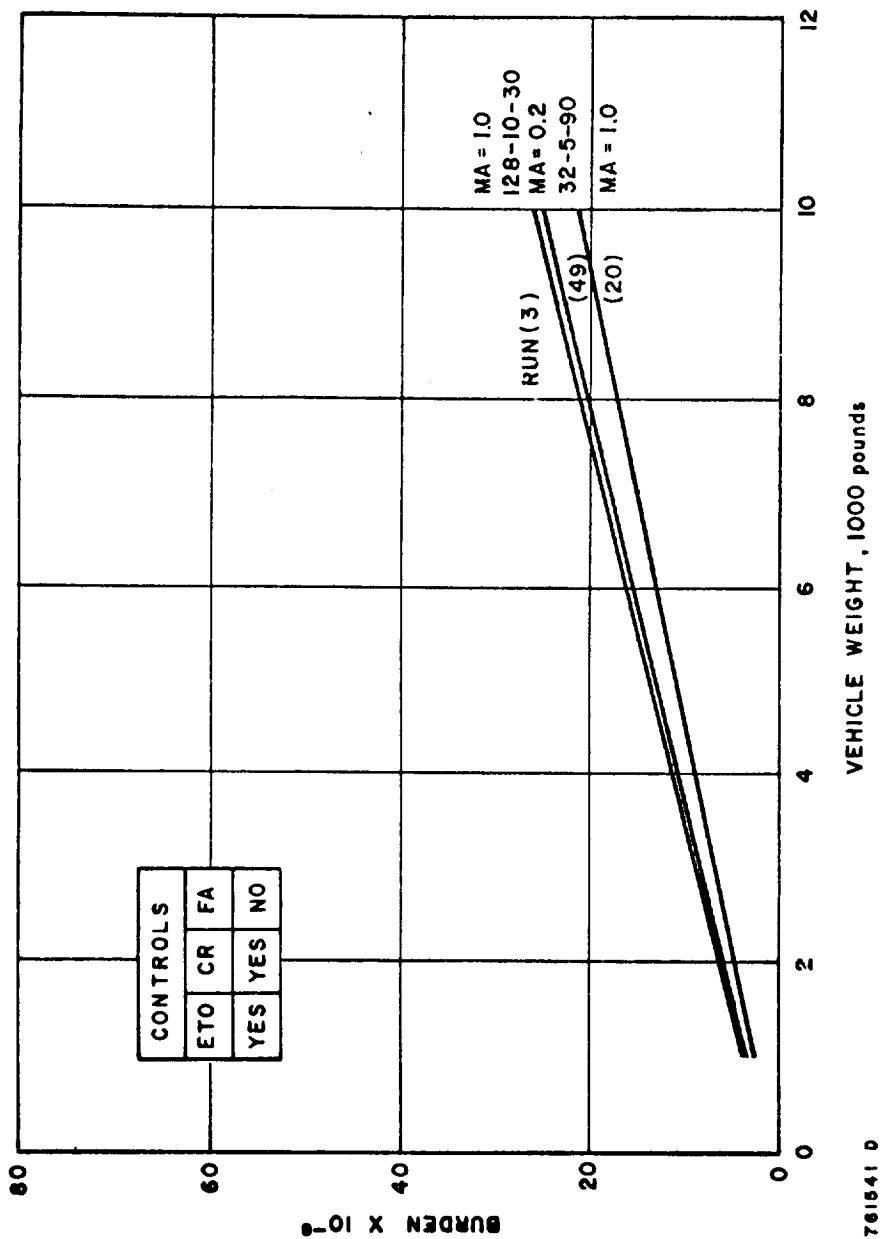


Figure 22 BURDEN VERSUS VEHICLE WEIGHT: ETO AND CLEAN ROOM ONLY

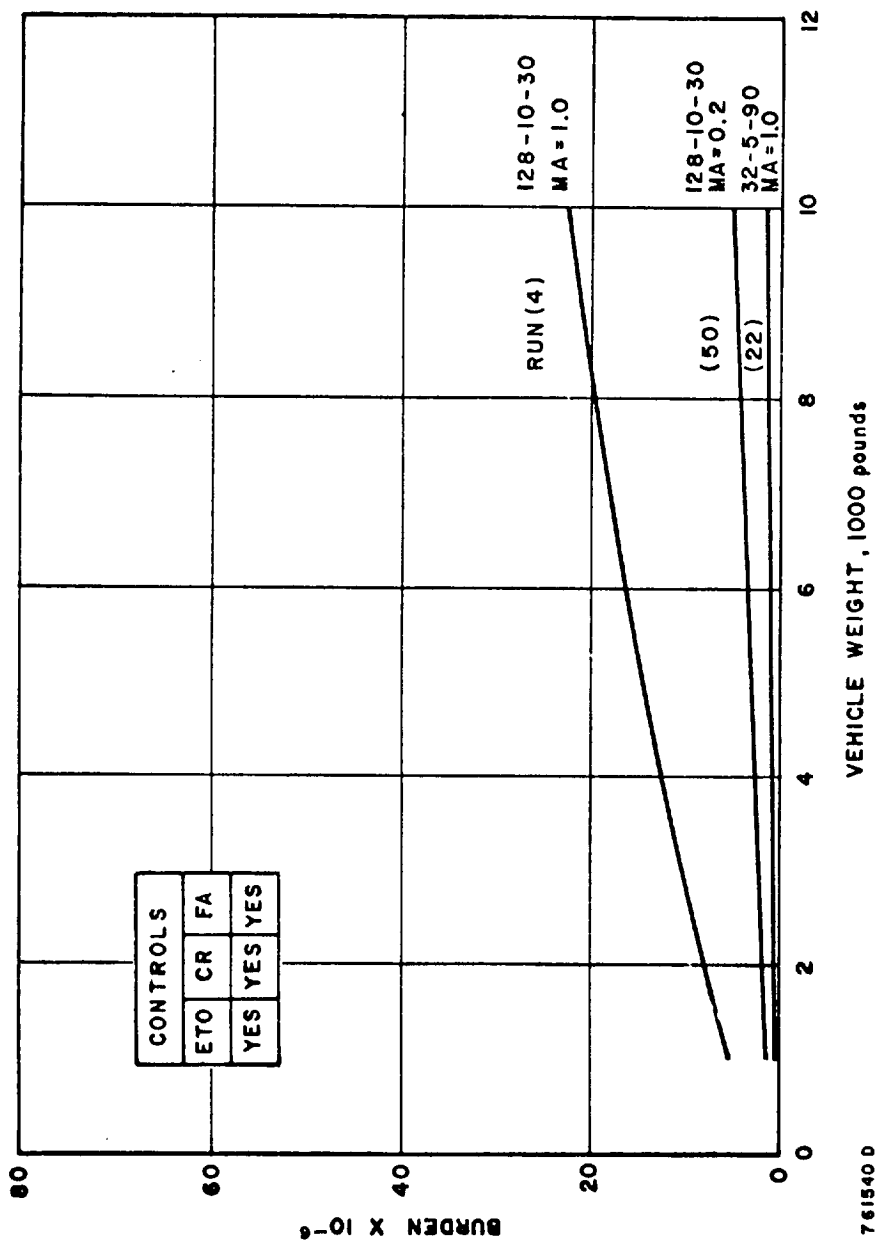


Figure 23 BURDEN VERSUS VEHICLE WEIGHT: ETO, CLEAN ROOM, AND FLIGHT ACCEPTANCE

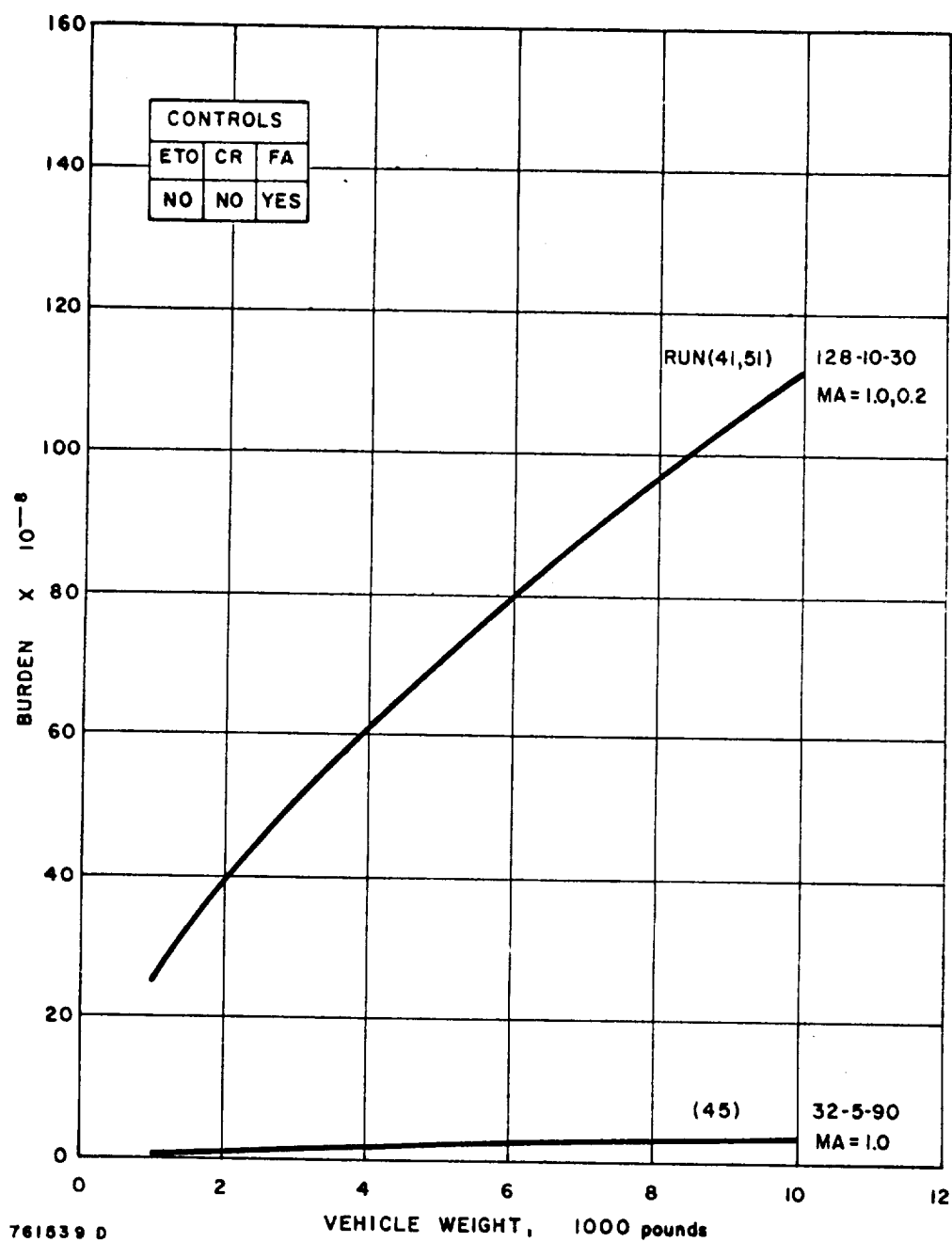


Figure 24 BURDEN VERSUS VEHICLE WEIGHT: FLIGHT ACCEPTANCE ONLY

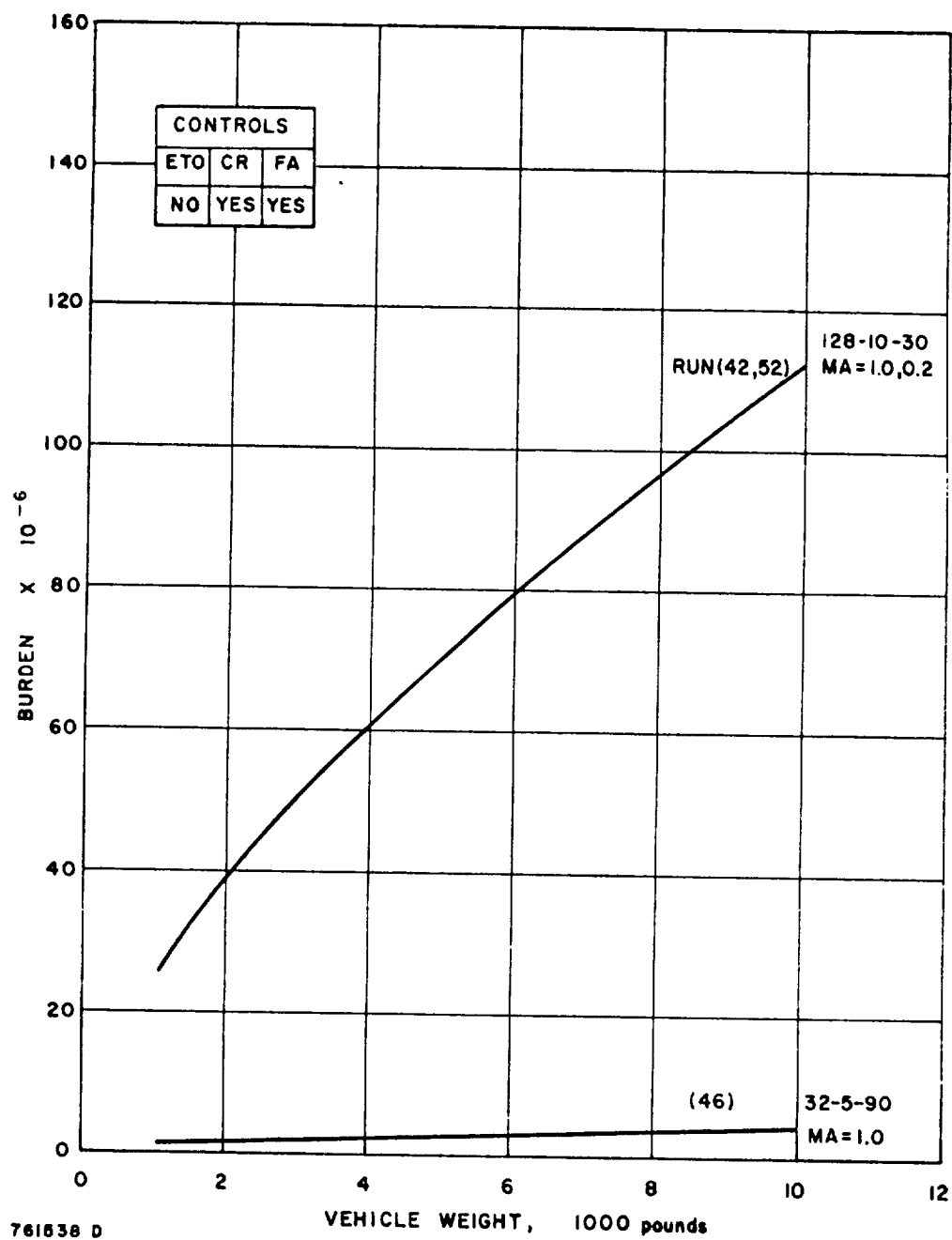


Figure 25 BURDEN VERSUS VEHICLE WEIGHT: CLEAN ROOM AND FLIGHT ACCEPTANCE ONLY

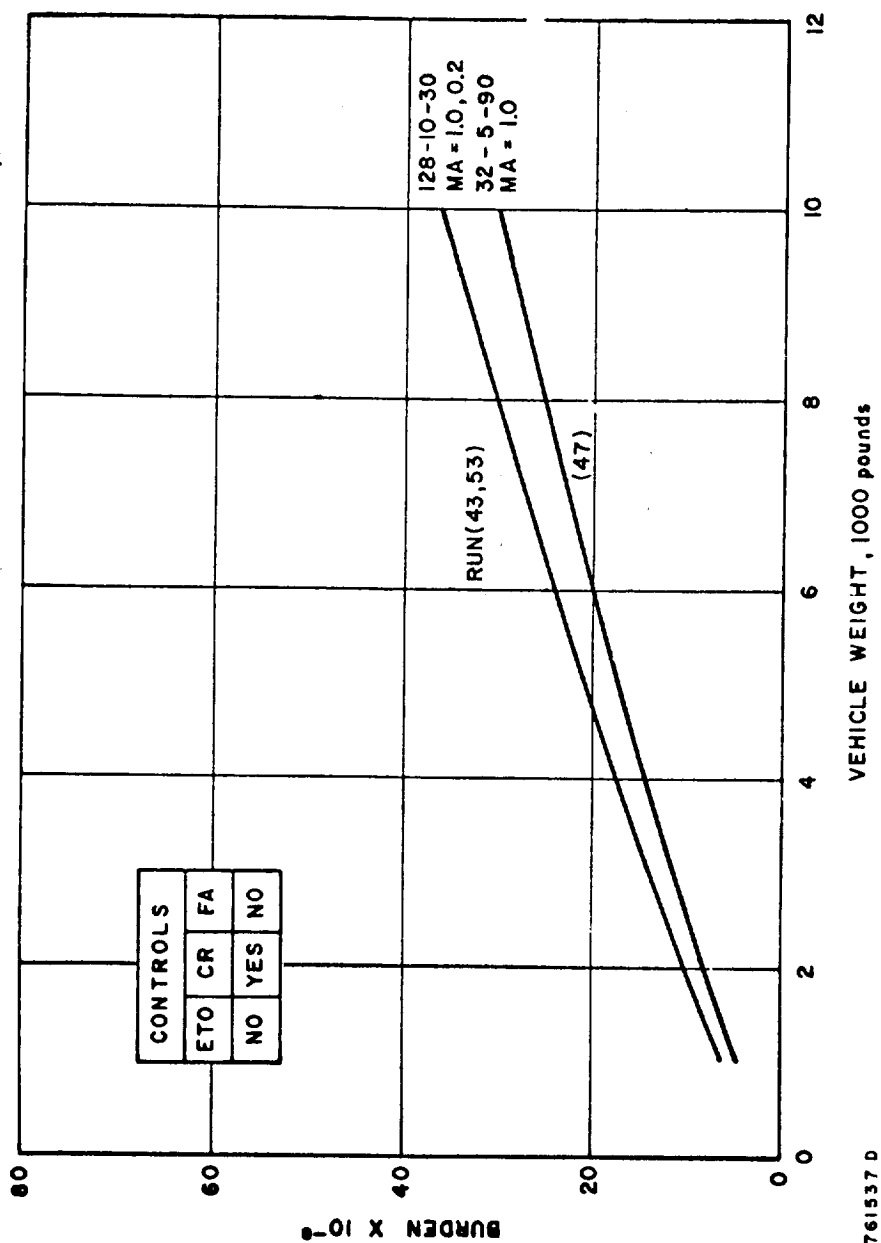


Figure 26 BURDEN VERSUS VEHICLE WEIGHT: CLEAN ROOM ONLY

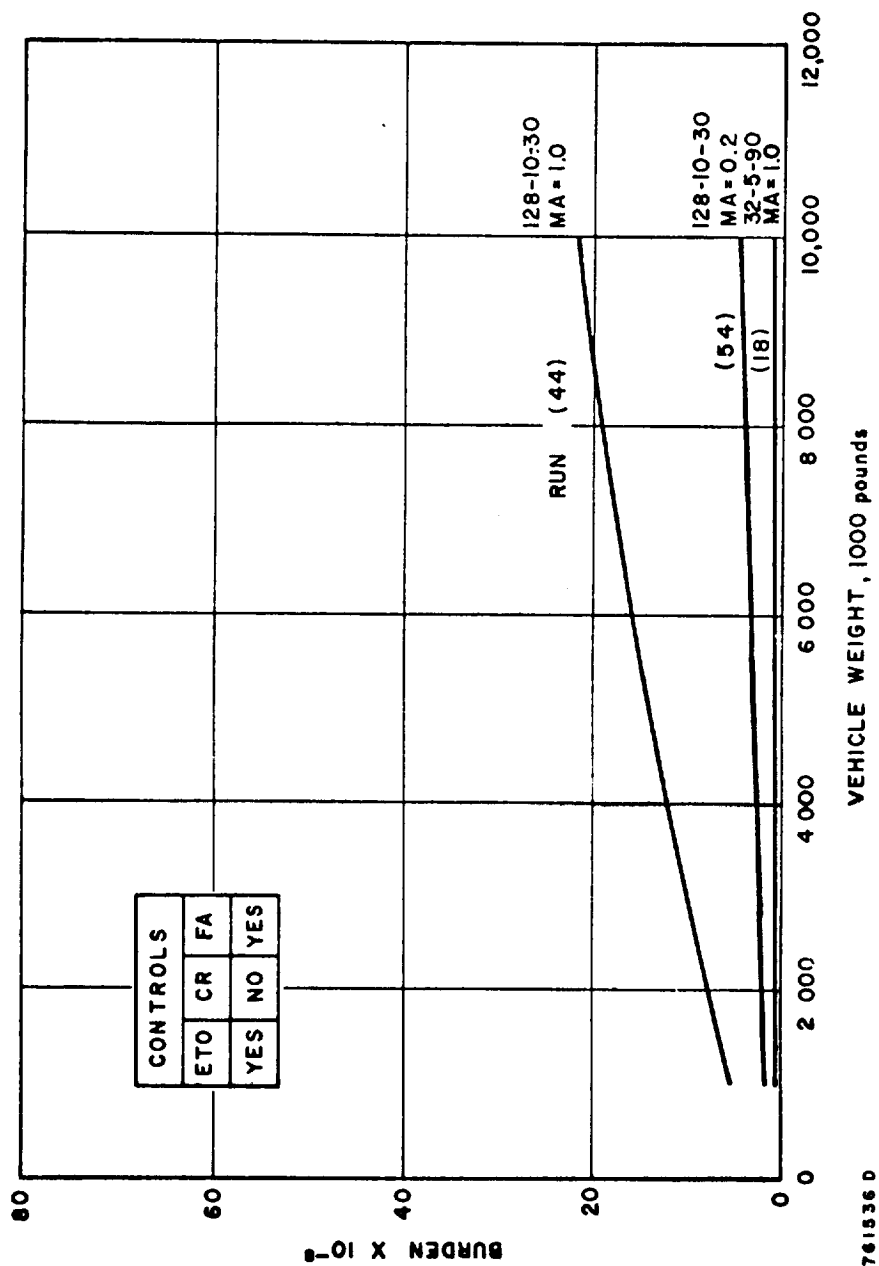
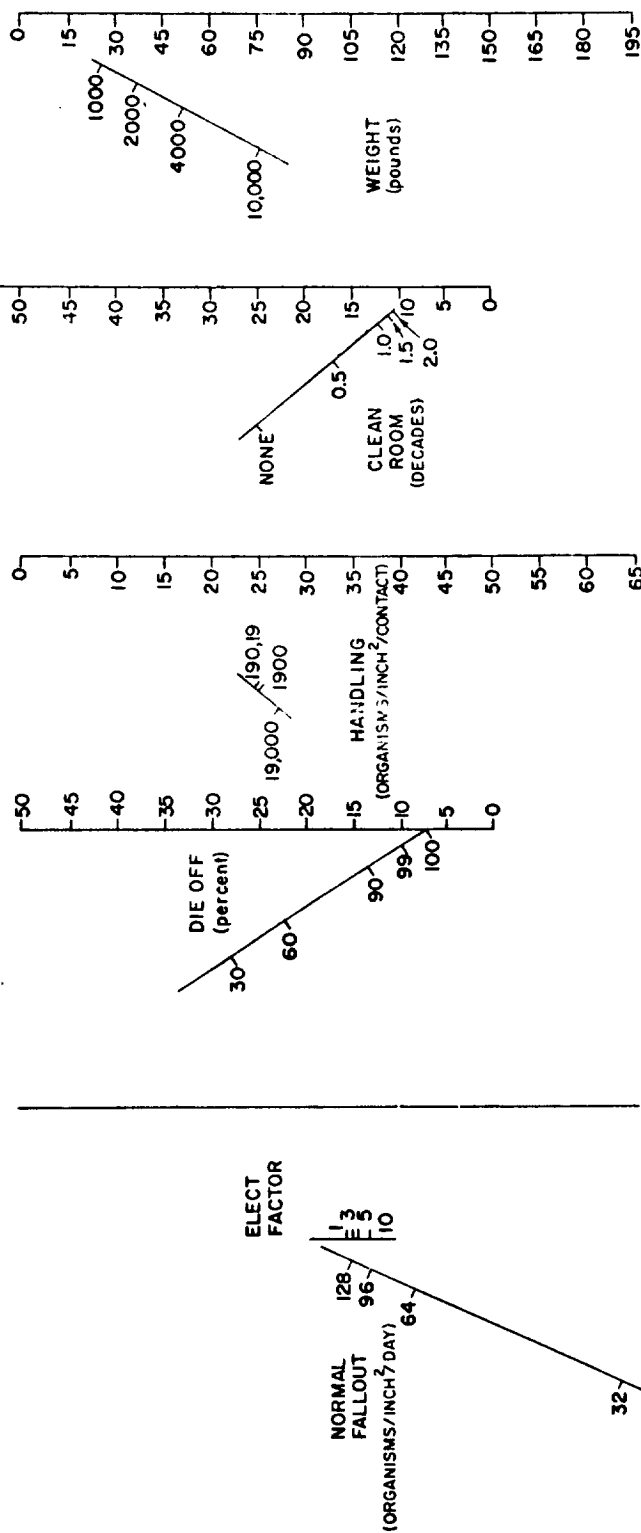


Figure 27 BURDEN VERSUS VEHICLE WEIGHT: ETO AND FLIGHT ACCEPTANCE ONLY

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Research Distribution Center (Lowell)	21

CONTROLS.			
ETO	CR	FA	
NO	NO	NO	



7615620

Figure 28 NOMOGRAM: NO CONTROLS

CONTROLS			
ETO	CR	FA	
YES	NO	NO	

BURDENS ~ ORGANISMS $\times 10^{-8}$

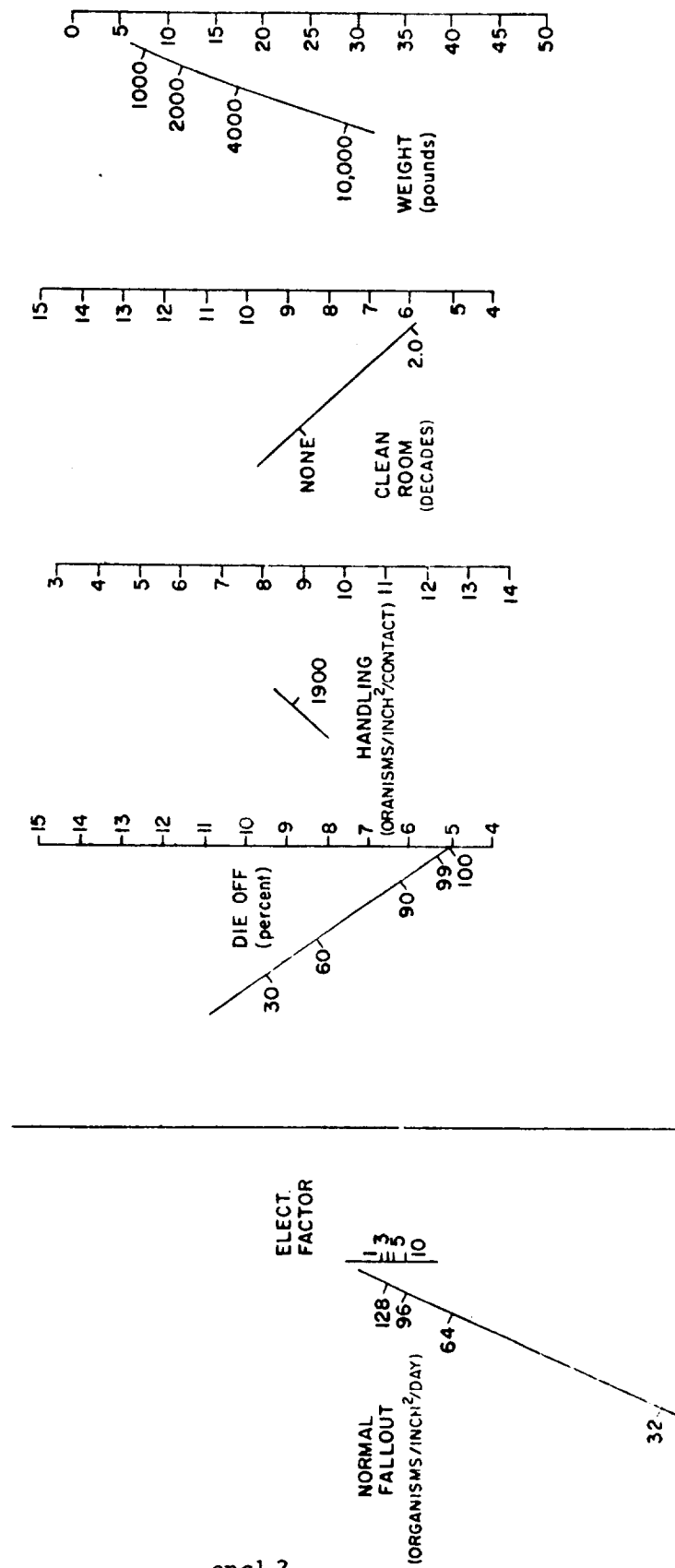
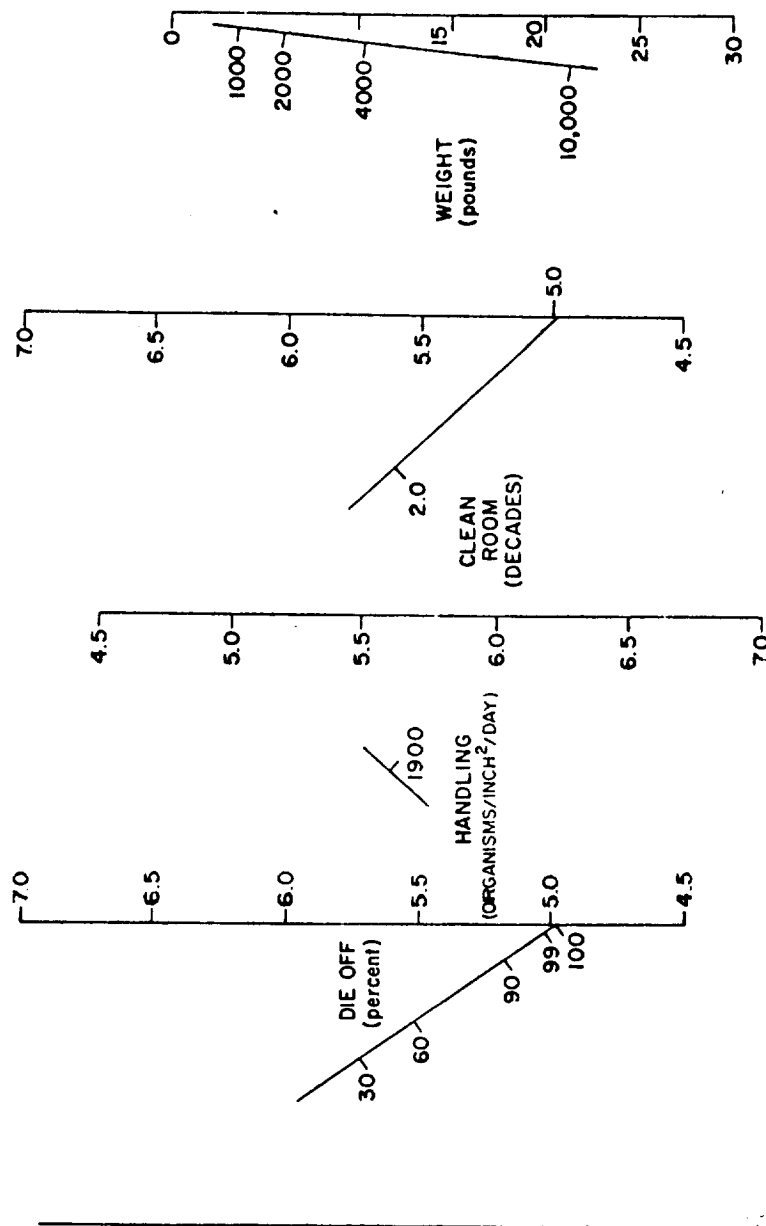


Figure 29 NOMOGRAM: ETO ONLY

BURDENS ~ ORGANISMS $\times 10^{-8}$



CONTROLS			
ETO	CR	FA	
YES	YES	NO	

ELECT
FACTOR

1
3
5
10

NORMAL
FALLOUT
(ORGANISMS/INCH²/DAY)

128
96
94

32

7615640

Figure 30 NOMOGRAM: ETO AND CLEAN ROOM ONLY

CONTROLS			
ETO	CR	FA	
YES	YES	YES	

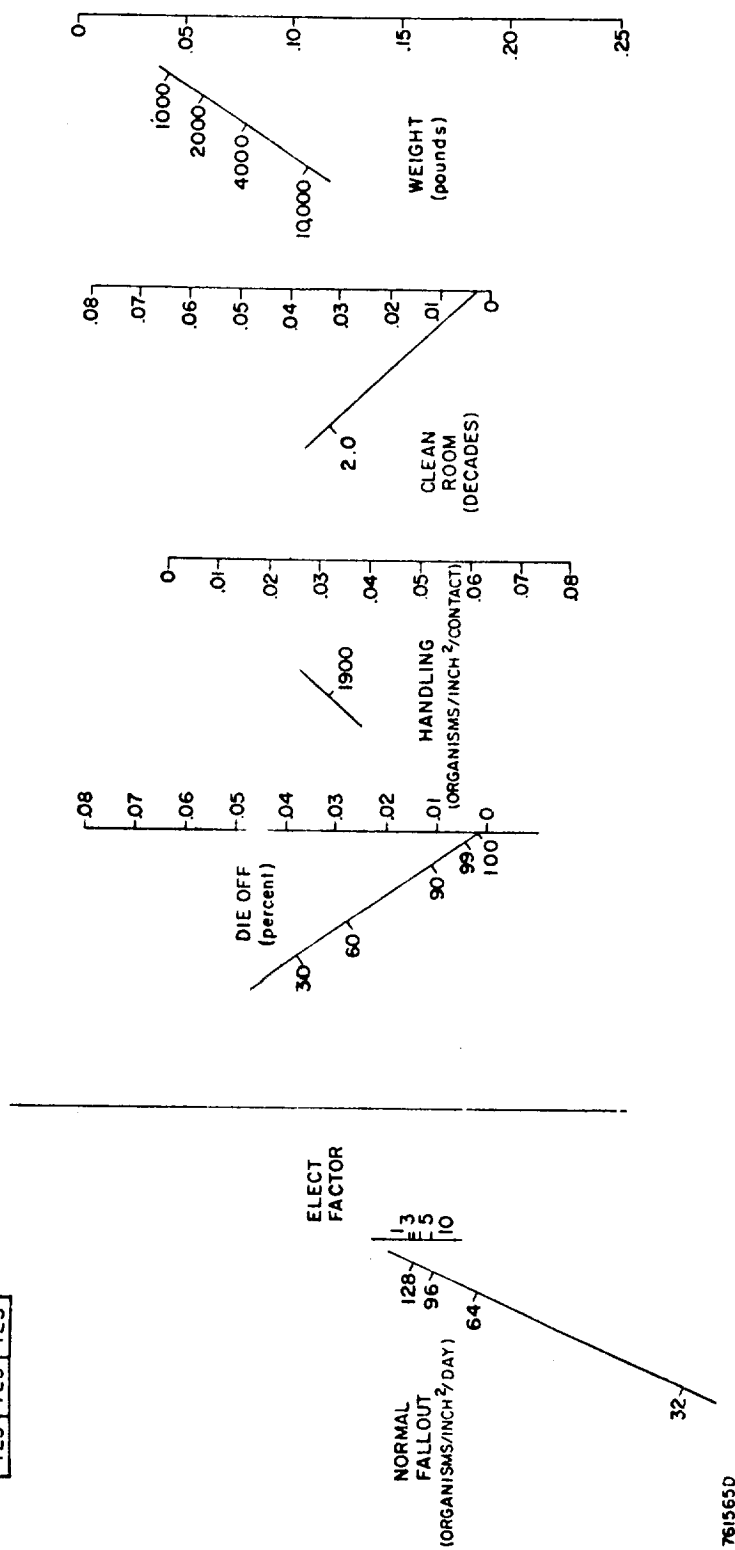
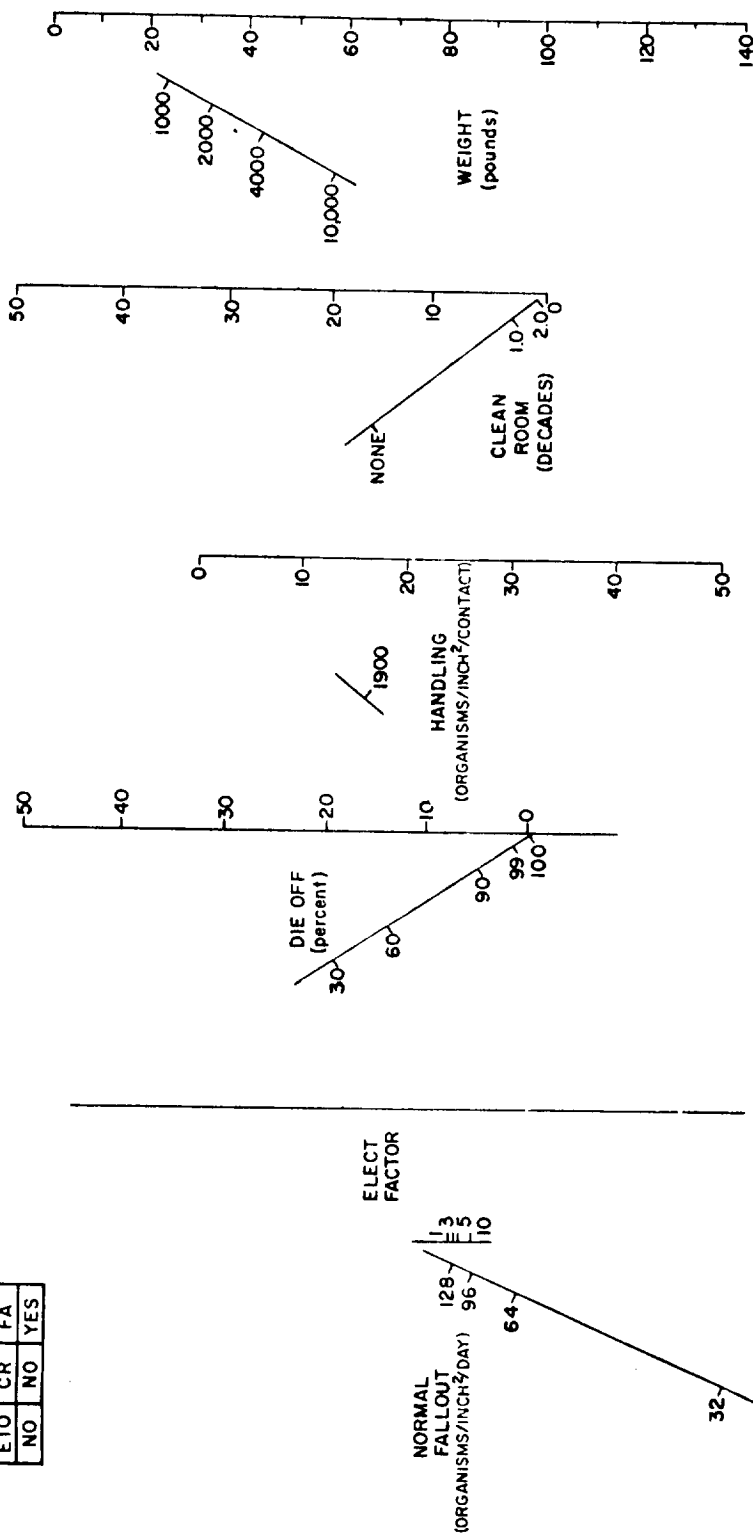


Figure 31 NOMOGRAM: ETO, CLEAN ROOM, AND FLIGHT ACCEPTANCE

CONTROLS			
ETO	CR	FA	
NO	NO	YES	



761566D

Figure 32 NOMOGRAM: F/A ONLY

CONTROLS			
ETO	CR	FA	
NO	YES	YES	

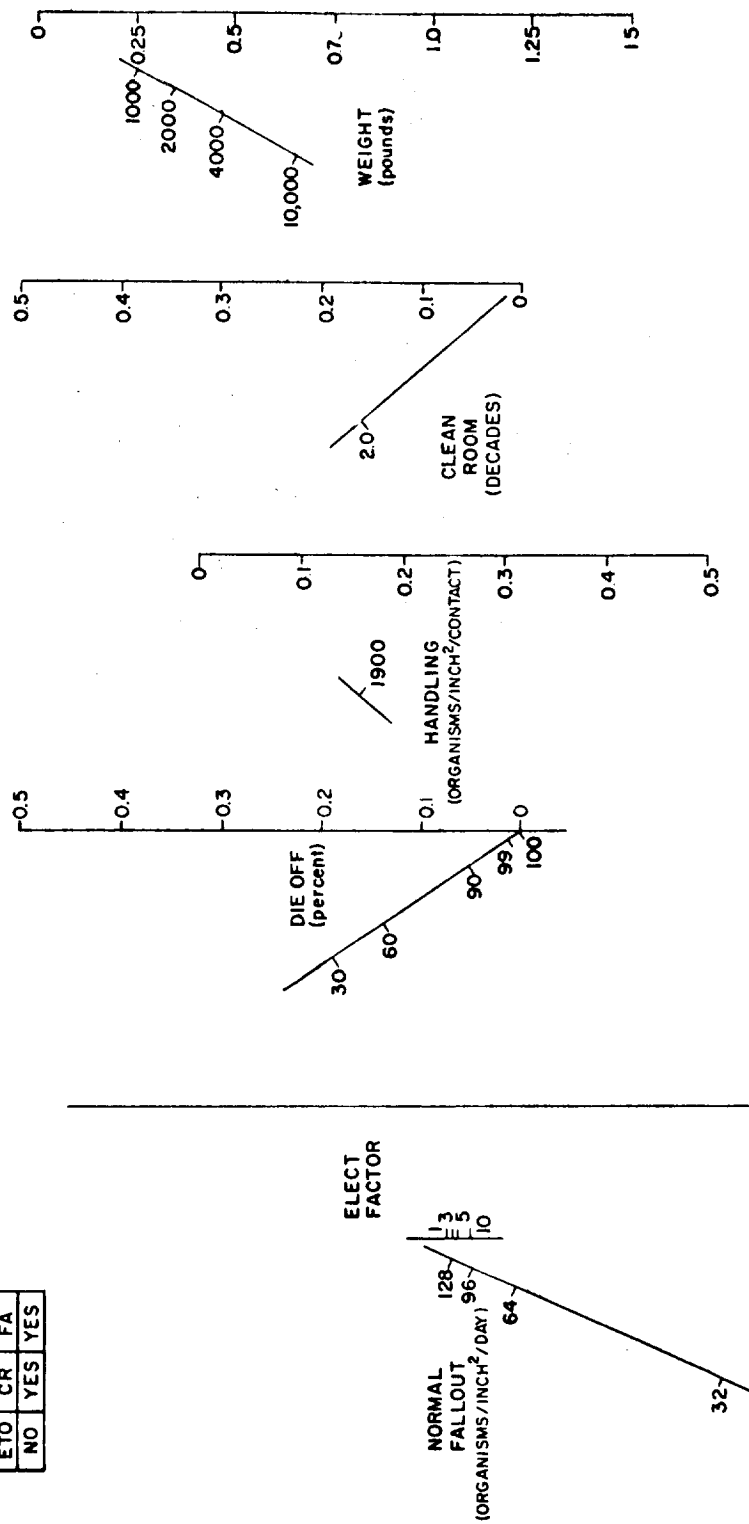


Figure 33 NOMOGRAM: CLEAN ROOM AND FLIGHT ACCEPTANCE ONLY

CONTROLS			
ETO	CR	FA	
NO	YES	YES	

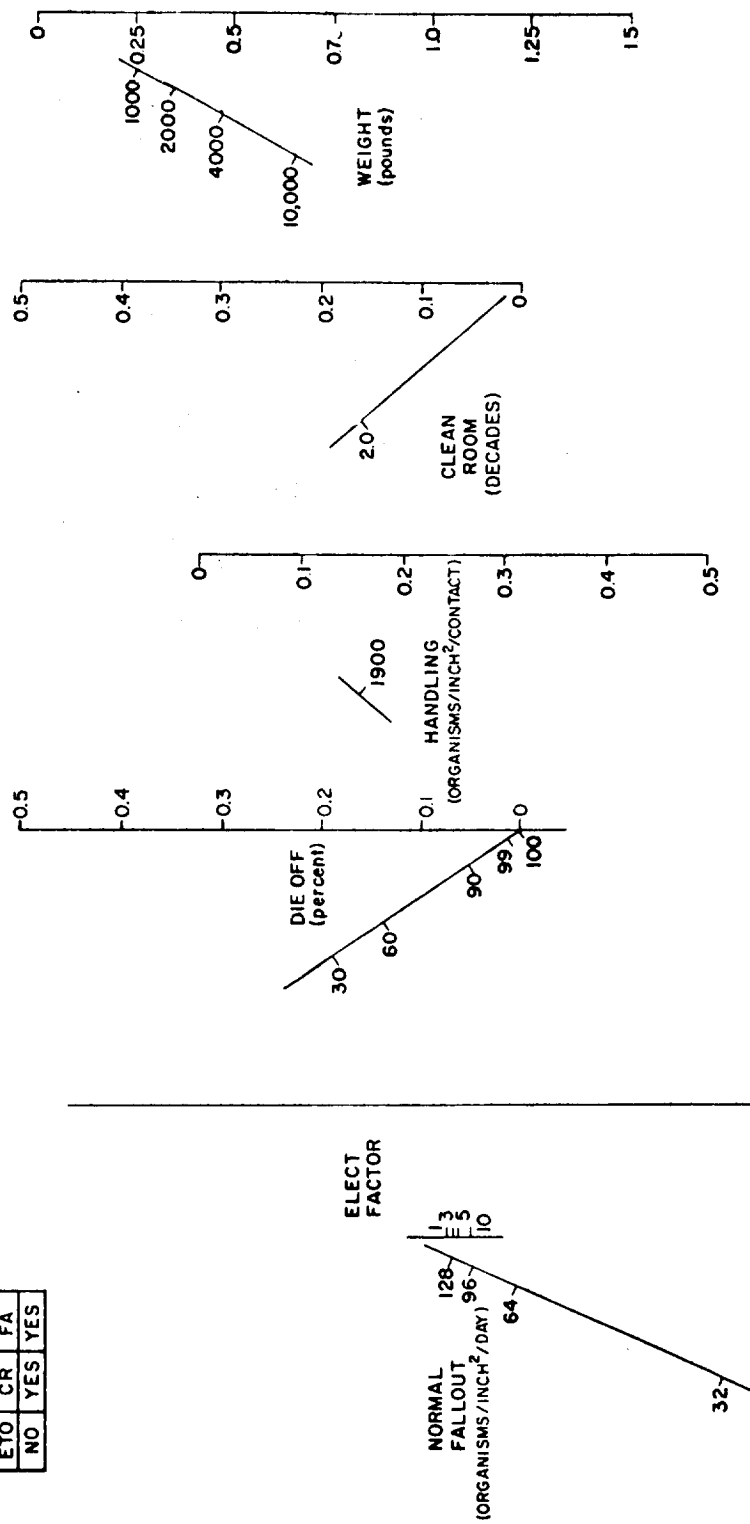
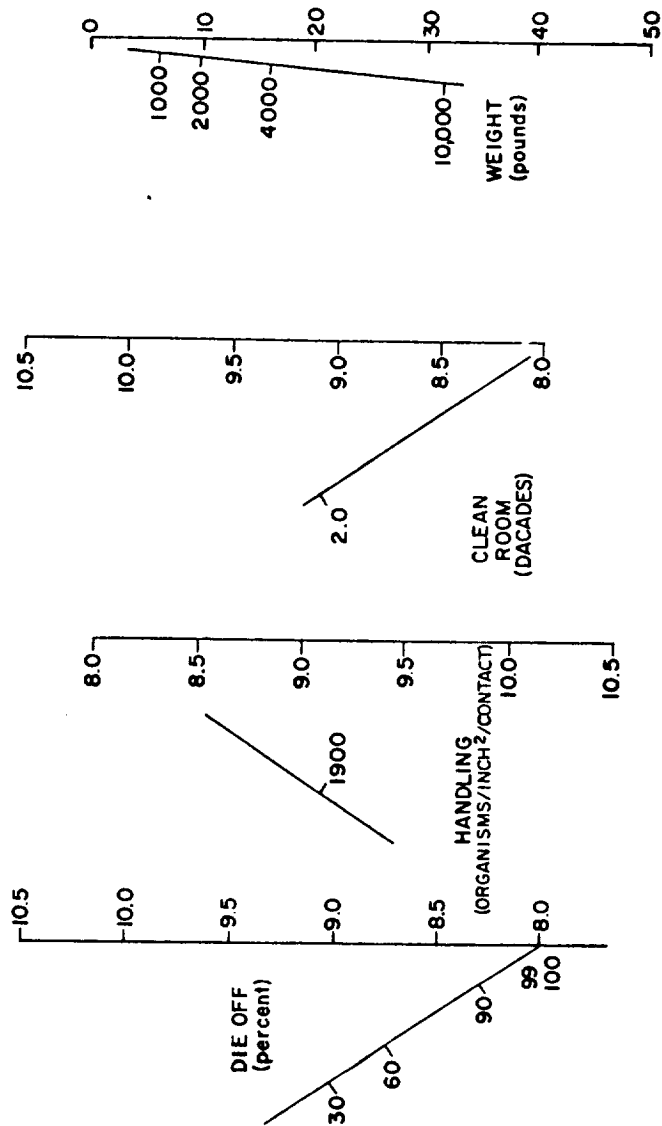


Figure 33 NOMOGRAM: CLEAN ROOM AND FLIGHT ACCEPTANCE ONLY

CONTROLS			
ETO	CR	FA	
NO	YES	NO	

BURDENS ~ ORGANISMS $\times 10^{-8}$



ELECT
FACTOR

13
5
10

NORMAL
FALLOUT
(ORGANISMS/INCH²/DAY)
128
96
64

32

761569D

Figure 34 NOMOGRAM: CLEAN ROOM ONLY

CONTROLS			
ETO	CR	FA	
YES	NO	YES	

BURDENS ~ ORGANISMS $\times 10^{-8}$

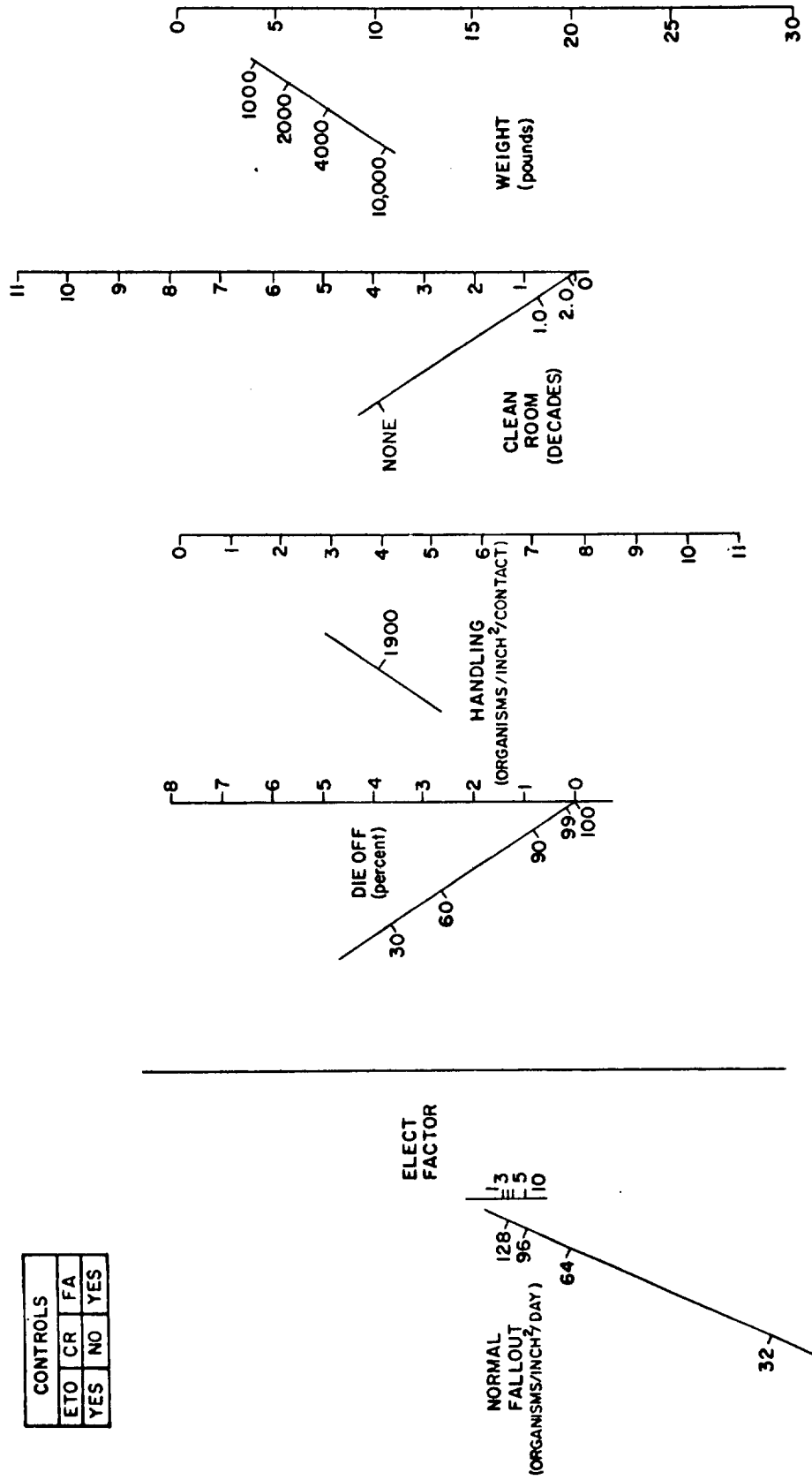


Figure 35 NOMOGRAM: ETO AND FLIGHT ACCEPTANCE ONLY